1. Trade name

TRILEPTAL® 300 mg Film-Coated Tablets
TRILEPTAL® 60 mg/mL Oral Suspension

2. Description and composition

Pharmaceutical forms

Film-coated tablet

Yellow, ovaloid slightly biconvex tablets, scored on both sides. Debossed with "TE", score, inverted "TE" on one side and "CG", score, inverted "CG" on the other side. The score line on Trileptal 300 mg film-coated tablets is to divide the tablet into equal doses.

Oral suspension

Off-white to slightly brown or slightly red oral suspension.

Active substance

Each film-coated tablet contains 300 mg oxcarbazepine.

1 mL of oral suspension contains 60 mg oxcarbazepine.

Excipients

Film-coated tablets

Tablet core:

Silica, colloidal anhydrous; cellulose, microcrystalline; hypromellose; crospovidone; magnesium stearate.

Tablet coating:

Hypromellose; talc; titanium dioxide (E171); macrogol 8000; iron oxide, yellow (E 172).

Trileptal oral suspension

Propyl parahydroxybenzoate; saccharin sodium; sorbic acid; macrogol stearate; methyl parahydroxybenzoate; yellow-plum-lemon aroma 39K 020; ascorbic acid; microcrystalline cellulose and carmellose sodium; propylene glycol; sorbitol, liquid (non-crystallising); water, purified.

Ethanol is a component of the flavour.

3. Indications

Trileptal® is indicated for the treatment of partial seizures (which include the seizure subtypes of simple, complex and partial seizures evolving to secondarily generalised seizures) and generalised tonic-clonic seizures, in adults and in children aged 5 years and above. Trileptal is suitable either as monotherapy or adjunctive therapy.

4. Dosage regimen and administration

Dosage regimen

Trileptal is suitable for use either as monotherapy or adjunctive therapy. In mono-and adjunctive therapy, treatment with Trileptal is initiated with a clinically effective dose given in two divided doses. The dose may be increased depending on the clinical response of the patient. In adjunctive therapy, as the total antiepileptic medicinal product load of the patient is increased, the dose of concomitant antiepileptic medicinal product(s) may need to be reduced and/or the Trileptal dose increased more slowly (see section 8 Interactions).

Trileptal oral suspension and Trileptal film-coated tablets are bioequivalent and may be interchanged at equal doses (see section 11 Clinical pharmacology).

The prescription for Trileptal oral suspension should be given in milliliters (see conversion table below which gives the milligram dose in milliliters).

Table-1 Dosage in milligrams vs. milliliters

Dose in milligrams (mg)	Dose in milliliters (mL)
10 mg	0.2 mL
20 mg	0.3 mL
30 mg	**0.5 mL**
40 mg	0.7 mL
50 mg	0.8 mL
60 mg	**1.0 mL**
70 mg	1.2 mL
80 mg	1.3 mL
90 mg	**1.5 mL**
100 mg	1.7 mL
200 mg	3.3 mL
300 mg	**5.0 mL**
400 mg	6.7 mL
500 mg	8.3 mL
600 mg	**10.0 mL**
700 mg	11.7 mL
800 mg	13.3 mL
900 mg	**15.0 mL**
1,000 mg	16.7 mL

General target population

Adults

Monotherapy and adjunctive therapy

Recommended initial dose

Trileptal should be initiated with a dose of 600 mg/day (8-10 mg/kg/day) given in 2 divided doses.

Maintenance dose

Therapeutic effects are seen at doses between 600 mg/day and 2,400 mg/day. If clinically indicated, the dose may be increased by a maximum of 600 mg/day at approximately weekly intervals from the starting dose to achieve the desired clinical response.

Maximum recommended dose

In a controlled hospital setting, dose increases up to 2,400 mg/day have been achieved over 48 hours.

Daily doses from 600 to 2,400 mg/day have been shown to be effective in a controlled adjunctive therapy trial, although most patients were not able to tolerate the 2,400 mg/day dose without reduction of concomitant antiepileptic medicinal products, mainly because of CNS-related adverse events.

Daily doses above 2,400 mg/day have not been studied systematically in clinical trials.

Special populations

Pediatric patients (below 18 years)

Recommended initial dose

In mono- and adjunctive therapy, Trileptal should be initiated with a dose of 8-10 mg/kg/day given in 2 divided doses.

Maintenance dose

In an adjunctive therapy trial in paediatric patients (aged 5 to 17 years), in which the intention was to reach a target daily dose of 46 mg/kg/day, the median daily dose was 31 mg/kg/day with a range of 6 to 51 mg/kg/day.

Maximum recommended dose

If clinically indicated, the dose may be increased by a maximum of 10 mg/kg/day at approximately weekly intervals from the starting dose, to a maximum daily dose of 45 mg/kg/day, to achieve the desired clinical response (see section 11 Clinical pharmacology).

Geriatric patients (65 years or above)

Adjustment of the dose is recommended in the elderly with compromised renal function (see Patients with renal impairment). For patients at risk of hyponatraemia see section 6 Warnings and precautions.

Hepatic impairment

No dosage adjustment is required for patients with mild to moderate hepatic impairment. Trileptal has not been studied in patients with severe hepatic impairment, therefore, caution should be exercised when dosing severely impaired patients (see sections 11 Clinical pharmacology and 6 Warnings and precautions).

Renal impairment

In patients with impaired renal function (creatinine clearance less than 30 mL/min) Trileptal therapy should be initiated at half the usual starting dose (300 mg/day) and

increased slowly, in at least weekly intervals to achieve the desired clinical response (see sections 11 Clinical pharmacology and 6 Warnings and precautions).

Method of administration

The following dosing recommendations apply to all patients, in the absence of impaired renal function (see section Pharmacokinetic properties). Drug plasma level monitoring is not necessary to optimise Trileptal therapy.

The oral suspension is suitable for younger children and other patients who cannot swallow tablets or where the required dose cannot be administered using tablets.

Trileptal can be taken with or without food (see section 11 Clinical pharmacology).

5. Contraindications

Known hypersensitivity to oxcarbazepine or eslicarbazepine or to any of the excipients of Trileptal.

Atrioventricular block.

History of previous bone marrow depression or of acute intermittent porphyria.

Impaired renal function.

6. Warnings and precautions

Hypersensitivity

Class I (immediate) hypersensitivity reactions including rash, pruritus, urticaria, angioedema and reports of anaphylaxis have been received in the post-marketing period. Cases of anaphylaxis and angioedema involving the larynx, glottis, lips and eyelids have been reported in patients after taking the first or subsequent doses of Trileptal. If a patient develops these reactions after treatment with Trileptal, the drug should be discontinued and an alternative treatment started.

Patients who have exhibited hypersensitivity reactions to carbamazepine should be informed that approximately 25-30 % of these patients may experience hypersensitivity reactions (e.g. severe skin reaction) with Trileptal (see section 7 Adverse drug reactions).

Hypersensitivity reactions, including multi-organ hypersensitivity reactions, may also occur in patients without history of hypersensitivity to carbamazepine. Such reactions can affect the skin, liver, blood and lymphatic system or other organs, either individually or together in the context of a systemic reaction (see section 7 Adverse drug reactions). In general, if signs and symptoms suggestive of hypersensitivity reactions occur, Trileptal should be withdrawn immediately.

Dermatological effects

Serious dermatological reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and erythema multiforme, have been reported very rarely in association with the use of Trileptal. Patients with serious dermatological reactions may require hospitalization, as these conditions may be life-threatening and very rarely be fatal. Trileptal associated cases occurred in both children and adults. The median time to onset was 19 days. Several isolated cases of recurrence of the serious

skin reaction when rechallenged with Trileptal were reported. Patients who develop a skin reaction with Trileptal should be promptly evaluated and Trileptal withdrawn immediately unless the rash is clearly not drug related. In case of treatment withdrawal, consideration should be given to replacing Trileptal with other antiepileptic drug therapy to avoid withdrawal seizures. Trileptal should not be restarted in patients who discontinued treatment due to a hypersensitivity reaction.

Association with HLA-B*1502

Retrospective studies in patients of Han Chinese and Thai origin found a strong correlation between SJS/TEN skin reactions associated with carbamazepine and the presence in these patients of the Human Leukocyte Antigen (HLA)-B*1502 allele. As the chemical structure of oxcarbazepine is similar to that of carbamazepine, there is a possibility that patients carrying the HLA-B*1502 allele also have an increased risk of SJS/TEN skin reactions with oxcarbazepine.

The frequency of HLA-B*1502 allele ranges from 2 to 12% in Han Chinese populations and is about 8% in Thai populations, and above 15% in the Philippines and some Malaysian populations. Allele frequencies up to about 2% and 6% have been reported in Korea and India, respectively. The frequency of the HLA-B*1502 allele is negligible in persons from European descent, several African populations, indigenous peoples of the Americas, Hispanic populations sampled and in Japanese (< 1%).

The allele frequencies listed here represent the percentage of chromosomes in the specified population that carry the allele of interest, meaning that the percentage of patients who carry a copy of the allele on at least one of their two chromosomes (i.e., the “carrier frequency”) is nearly twice as high as the allele frequency. Therefore, the percentage of patients who may be at risk is nearly twice the allele frequency.

Testing for the presence of the HLA-B*1502 allele should be considered in patients with ancestry in genetically at-risk populations, prior to initiating treatment with Trileptal (see below Information for healthcare professionals). The use of Trileptal should be avoided in tested patients who are found to be positive for HLA-B*1502 unless the benefits clearly outweigh the risks. HLA-B*1502 may be a risk factor for the development of SJS/TEN in Chinese patients taking other anti-epileptic drugs (AED) associated with SJS/TEN. Consideration should therefore be given to avoid use of other drugs associated with SJS/TEN in HLA-B*1502 positive patients, when alternative therapies are otherwise equally acceptable. Screening is not generally recommended in patients from populations in which the prevalence of HLA-B*1502 is low or in current Trileptal users, as the risk of SJS/TEN is largely confined to the first few months of therapy, regardless of HLA-B*1502 status.

Association with HLA-A*3101

Human Leukocyte Antigen (HLA)-A*3101 may be a risk factor for the development of cutaneous adverse drug reactions such as SJS, TEN, DRESS, AGEP and maculopapular rash.

The frequency of the HLA-A*3101 allele varies widely between ethnic populations and its frequency is about 2 to 5% in European populations and is about 10% in the Japanese population. The frequency of this allele is estimated to be less than 5% in the majority of Australian, Asian, African and North American populations with some exceptions within 5 to 12%. Frequency above 15% has been estimated in some ethnic groups in

South America (Argentina and Brazil), North America (US Navajo and Sioux, and Mexico Sonora Seri) and Southern India (Tamil Nadu) and between 10% to 15% in other native ethnicities in these same regions.

The allele frequencies listed here represent the percentage of chromosomes in the specified population that carry the allele of interest, meaning that the percentage of patients who carry a copy of the allele on at least one of their two chromosomes (i.e., the "carrier frequency") is nearly twice as high as the allele frequency. Therefore, the percentage of patients who may be at risk is nearly twice the allele frequency.

There is some data that suggest HLA-A*3101 is associated with an increased risk of carbamazepine-induced cutaneous adverse drug reactions including SJS, TEN, Drug rash with eosinophilia (DRESS), or less severe acute generalized exanthematous pustulosis (AGEP) and maculopapular rash.

There are insufficient data to support a recommendation for testing the presence of HLA-A*3101 allele in patients, prior to initiating treatment with oxcarbazepine. Genetic screening is generally not recommended for any current Trileptal users, as the risk of SJS/TEN, AGEP, DRESS and maculopapular rash is largely confined to the first few months of therapy, regardless of HLA-A*3101 status.

Limitation of genetic screening

Genetic screening results must never substitute for appropriate clinical vigilance and patient management. Many Asian patients positive for HLA-B*1502 and treated with Trileptal will not develop SJS/TEN and patients negative for HLA-B*1502 of any ethnicity can still develop SJS/TEN. Similarly many patients positive for HLA-A*3101 and treated with Trileptal will not develop SJS, TEN, DRESS, AGEP or maculopapular rash and patients negative for HLA-A*3101 of any ethnicity can still develop these severe cutaneous adverse reactions. The role of other possible factors in the development of, and morbidity from, these severe cutaneous adverse reactions, such as AED dose, compliance, concomitant medications, co-morbidities, and the level of dermatologic monitoring have not been studied.

Information for the healthcare professionals

If testing for the presence of the HLA-B*1502 allele is performed, high-resolution "HLA-B*1502 genotyping" is recommended. The test is positive if either one or two HLA-B*1502 alleles are detected and negative if no HLA-B*1502 alleles are detected. Similarly if testing for the presence of the HLA-A*3101 allele is performed, high resolution "HLA-A*3101 genotyping" respectively is recommended. The test is positive if either one or two HLA-A*3101 alleles are detected and negative if no HLA-A*3101 alleles are detected.

Risk of seizure aggravation

Risk of seizure aggravation has been reported with Trileptal. The risk of seizure aggravation is seen especially in children but may also occur in adults. In case of seizure aggravation, Trileptal should be discontinued.

Hyponatremia

Serum sodium levels below 125 mmol/L, usually asymptomatic and not requiring adjustment of therapy, have been observed in up to 2.7 % of Trileptal treated patients.

Experience from clinical trials shows that serum sodium levels returned towards normal when the Trileptal dosage was reduced, discontinued or the patient was treated conservatively (e.g. restricted fluid intake).

In patients with pre-existing renal conditions associated with low sodium levels (e.g. inappropriate ADH secretion like syndrome) or in patients treated concomitantly with sodium-lowering medicinal products (e.g. diuretics, drugs associated with inappropriate ADH secretion, desmopressin), as well as NSAIDs (e.g. indometacin), serum sodium levels should be measured prior to initiating therapy. Thereafter, serum sodium levels should be measured after approximately two weeks and then at monthly intervals for the first three months during therapy, or according to clinical need. These risk factors may apply especially to elderly patients.

For patients on Trileptal therapy when starting on sodium-lowering drugs, the same approach for sodium checks should be followed. In general, if clinical symptoms suggestive of hyponatraemia occur on Trileptal therapy (see section 7 Adverse drug reactions), serum sodium measurement may be considered. Other patients may have serum sodium assessed as part of their routine laboratory studies.

All patients with cardiac insufficiency and secondary heart failure should have regular weight measurements to determine occurrence of fluid retention. In case of fluid retention or worsening of the cardiac condition, serum sodium levels should be checked. If hyponatraemia is observed, water restriction is an important counter-measure. As oxcarbazepine may, very rarely, lead to impairment of cardiac, patients with pre-existing conduction disturbances (e.g. AV-block, arrhythmia) should be monitored carefully.

Hepatic function

Very rare cases of hepatitis have been reported, which in most cases resolved favourably. When a hepatic event is suspected, liver function should be evaluated and discontinuation of Trileptal should be considered. Caution should be exercised when treating patients with severe hepatic impairment (see sections 4 Dosage regimen and administration and 11 Clinical pharmacology).

Renal function

In patients with impaired renal function (creatinine clearance less than 30 mL/min), caution should be exercised during Trileptal treatment especially with regard to the starting dose and up titration of the dose (see sections 4 Dosage regimen and administration and 11 Clinical pharmacology).

Hematological effects

Very rare reports of agranulocytosis, aplastic anemia and pancytopenia have been seen in patients treated with Trileptal during post-marketing experience (see section 7 Adverse drug reactions). However, due to the very low incidence of these conditions and confounding factors (e.g. underlying disease, concomitant medication), causality cannot be established.

Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.

Suicidal ideation and behavior

Suicidal ideation and behavior have been reported in patients treated with antiepileptic agents in several indications. A meta-analysis of randomized placebo controlled trials of antiepileptic drugs has shown a small increased risk of suicidal ideation and behaviour. The mechanism of this risk is not known.

Therefore patients should be monitored for signs of suicidal ideation and behavior and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge.

Interactions

Hormonal contraceptives

Female patients of childbearing age should be warned that the concurrent use of Trileptal with hormonal contraceptives may render this type of contraception ineffective (see sections 8 Interactions and 9 Pregnancy, lactation, females and males of reproductive potential). Additional non-hormonal forms of contraception are recommended when using Trileptal.

Alcohol

Caution should be exercised if alcohol is taken in combination with Trileptal therapy, due to a possible additive sedative effect.

Withdrawal effects

As with all antiepileptic drugs, Trileptal should be withdrawn gradually to minimize the potential of increased seizure frequency.

Effects on ability to drive and use machines

The use of Trileptal has been associated with adverse reactions such as dizziness or somnolence (see section 7 Adverse drug reactions). Therefore, patients should be advised that their physical and/or mental abilities required for operating machinery or driving a car might be impaired.

7. Adverse drug reactions

Summary of the safety profile

The most commonly reported adverse reactions are somnolence, headache, dizziness, diplopia, nausea, vomiting and fatigue occurring in more than 10 % of patients.

In clinical trials, adverse events (AEs) were generally mild to moderate in severity, of transient nature and occurred predominantly at the start of treatment.

The analysis of the undesirable effect profile by body system is based on AEs from clinical trials assessed as related to Trileptal. In addition, clinically meaningful reports on adverse experiences from named patient programs and post-marketing experience were taken into account.

Tabulated summary of adverse drug reactions from clinical trials

Adverse drug reactions from clinical trials (Table-2) are listed by MedDRA system organ class. Within each system organ class, the adverse drug reactions are ranked by

frequency, with the most frequent reactions first. Within each frequency grouping, adverse drug reactions are presented in order of decreasing seriousness. In addition, the corresponding frequency category for each adverse drug reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Table-2 Adverse drug reactions from clinical trials

Blood and lymphatic system disorders	
Uncommon	Leucopenia.
Very rare	Bone marrow depression, agranulocytosis, aplastic anemia, pancytopenia, neutropenia, thrombocytopenia.
Immune system disorders	
Very rare	Hypersensitivity (including multi-organ hypersensitivity) characterised by features such as rash, fever. Other organs or systems may be affected such as blood and lymphatic system (e.g. eosinophilia, thrombocytopenia, leucopenia, lymphadenopathy, splenomegaly), liver (e.g. abnormal liver function tests, hepatitis), muscles and joints (e.g. joint swelling, myalgia, arthralgia), nervous system (e.g. hepatic encephalopathy), kidney (e.g. proteinuria, nephritis interstitial, renal failure), lungs (e.g. dyspnea, pulmonary oedema, asthma, bronchospasms, interstitial lung disease), angioedema, anaphylactic reactions.
Endocrine disorders	
Common	Weight increased
Very rare	Hypothyroidism
Metabolism and nutrition disorders	
Common	Hyponatraemia.
Very rare	Hyponatraemia* associated with signs and symptoms such as seizures, confusion, depressed level of consciousness, encephalopathy (see also Nervous system disorders for further undesirable effects), vision disorders (e.g. blurred vision), vomiting, nausea, folic acid deficiency.
Psychiatric disorders	
Common	Confusional state, depression, apathy, agitation (e.g. nervousness), affect lability.
Nervous system disorders	
Very common	Somnolence, headache, dizziness.
Common	Ataxia, tremor, nystagmus, disturbance in attention, amnesia, apathy, agitation (e.g. nervousness), affect lability, irritability
Eye disorders	
Very common	Diplopia.
Common	Vision blurred, visual disturbance.
Ear and labyrinth disorders	
Common	Vertigo.
Cardiac disorders	
Very rare	Arrhythmia, atrioventricular block.
Vascular disorders	
Very rare	Hypertension.
Gastrointestinal disorders	
Very common	Nausea, vomiting.
Common	Diarrhoea, constipation, abdominal pain.
Very rare	Pancreatitis and/or lipase and/or amylase increase.
Hepatobiliary disorders	

Very rare	Hepatitis.
Skin and subcutaneous tissue disorders	
Common	Rash, alopecia, acne.
Uncommon	Urticaria.
Very rare	Angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), erythema multiforme.
Musculoskeletal, connective tissue and bone disorders	
Very rare	Systemic lupus erythematosus.
General disorders and administration site conditions	
Very common	Fatigue.
Common	Asthenia.
Investigations	
Common	Blood uric acid increased
Uncommon	Hepatic enzymes increased, blood alkaline phosphatase increased.
Very rare	Amylase increase, lipase increase

*Very rarely clinically significant hyponatraemia (sodium < 125 mmol/L) can develop during Trileptal use. It generally occurred during the first 3 months of treatment with Trileptal, although there were patients who first developed a serum sodium < 125 mmol/L more than 1 year after initiation of therapy (see section 6 Warnings and precautions).

Adverse drug reactions from spontaneous reports and literature cases (frequency not known)

The following adverse drug reactions have been derived from post-marketing experience with Trileptal via spontaneous case reports and literature cases. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorized as not known. Adverse drug reactions are listed according to system organ classes in MedDRA. Within each system organ class, ADRs are presented in order of decreasing seriousness.

Metabolism and nutrition disorders

Inappropriate ADH secretion like syndrome with signs and symptoms of lethargy, nausea, dizziness, decrease in serum (blood) osmolality, vomiting, headache, confusional state or other neurological signs and symptoms.

Skin and subcutaneous tissue disorders

Drug rash with eosinophilia and systemic symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP).

Injury, poisoning and procedural complications

Fall.

Nervous system disorders

Speech disorders (including dysarthria); more frequent during up titration of Trileptal dose.

Musculoskeletal, connective tissue and bone disorders

There have been reports of decreased bone mineral density, osteopenia, osteoporosis and fractures in patients on long-term therapy with Trileptal. The mechanism by which oxcarbazepine affects bone metabolism has not been identified.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

or

Novartis Indonesia
Website: www.novartis.com/report

8. Interactions

Enzyme inhibition

Oxcarbazepine was evaluated in human liver microsomes to determine its capacity to inhibit the major cytochrome P450 enzymes responsible for the metabolism of other drugs. The results demonstrate that oxcarbazepine and its pharmacologically active metabolite (the monohydroxy derivative, MHD) inhibit CYP2C19. Therefore, interactions could arise when co-administering high doses of Trileptal with drugs that are metabolized by CYP2C19 (e.g. phenobarbital, phenytoin, see below). In some patients treated with Trileptal and drugs metabolized via CYP2C19 dose reduction of the co-administered drugs might be necessary.

In human liver microsomes, oxcarbazepine and MHD have little or no capacity to function as inhibitors for the following enzymes: CYP1A2, CYP2A6, CYP2C9, CYP2D6, CYP2E1, CYP4A9 and CYP4A11.

Enzyme induction

Oxcarbazepine and MHD induce *in vitro* and *in vivo*, cytochromes CYP3A4 and CYP3A5 responsible for the metabolism of dihydropyridine calcium antagonists, oral contraceptives, and antiepileptic drugs (e.g. carbamazepine) resulting in a lower plasma concentration of these drugs (see below). A decrease in plasma concentrations may also be observed for other drugs mainly metabolized by CYP3A4 and CYP3A5, for example immunosuppressants (e.g. ciclosporin, tacrolimus).

In vitro, oxcarbazepine and MHD are weak inducers of UDP-glucuronyl transferase. Therefore, *in vivo* they are unlikely to have an effect drugs which are mainly eliminated by conjugation through the UDP-glucuronyl transferases (e.g. valproic acid, lamotrigine). When initiating treatment with Trileptal or changing the dose, it may take 2 or 3 weeks to reach the new level of induction. In the case of discontinuation of Trileptal therapy, a dose reduction of the concomitant medication may be necessary and

should be decided upon by clinical and/or plasma level monitoring. The induction is likely to gradually decrease over 2 or 3 weeks after discontinuation.

Induction studies conducted with human hepatocytes confirmed oxcarbazepine and MHD as weak inducers of isoenzymes of the 2B and 3A4 CYP sub-family. The induction potential of oxcarbazepine/MHD on other CYP isoenzymes is not known.

Antiepileptic drugs and enzyme inducing drugs

Potential interactions between Trileptal and other antiepileptic drugs were assessed in clinical studies. The effect of these interactions on mean AUCs and C_{min} are summarised in the following table.

Summary of antiepileptic drugs interactions with Trileptal

Antiepileptic drugs	Influence of Trileptal on antiepileptic drugs	Influence of antiepileptic drugs on MHD
Co-administered	Concentration	Concentration
Carbamazepine	0 to 22 % decrease (30 % increase of carbamazepine-epoxide)	40 % decrease
Clobazam	Not studied	No influence
Felbamate	Not studied	No influence
Phenobarbital	14 to 15 % increase	30 to 31 % decrease
Phenytoin	0 to 40 % increase	29 to 35 % decrease
Valproic acid	No influence	0 to 18 % decrease
Lamotrigine	No influence	No influence

In vivo, plasma levels of phenytoin increased by up to 40 %, when Trileptal was given at doses above 1,200 mg/day. Therefore, when using doses of Trileptal greater than 1,200 mg/day during adjunctive therapy, a decrease in the dose of phenytoin may be required (see section 4 Dosage regimen and administration). The increase in the phenobarbital level, however, is small (15 %) when given with Trileptal.

Strong inducers of cytochrome P450 enzymes and/or UGT (e.g. rifampicin, carbamazepine, phenytoin and phenobarbital) have been shown to decrease the plasma/serum levels of MHD (29 to 49 %) in adults; in children 4 to 12 years of age, MHD clearance increased approximately 35% when given one of the three enzyme-inducing antiepileptic medicinal products compared to monotherapy. Concomitant therapy of Trileptal and lamotrigine has been associated with an increased risk of adverse events (nausea, somnolence, dizziness and headache). When one or several antiepileptic medicinal products are concurrently administered with Trileptal, a careful dose adjustment and/or plasma level monitoring may be considered on a case by case basis, notably in paediatric patients treated concomitantly with lamotrigine.

No autoinduction has been observed with Trileptal.

Hormonal contraceptives

Trileptal was shown to have an influence on the two components, ethinylestradiol (EE) and levonorgestrel (LNG), of an oral contraceptive. The mean AUC values of EE and LNG were decreased by 48 to 52 % and 32 to 52 %, respectively. Studies with other oral or implant contraceptives have not been conducted. Therefore, concurrent use of Trileptal with hormonal contraceptives may render these contraceptives ineffective (see sections 6 Warnings and precautions and 9 Pregnancy, lactation, females and males of reproductive potential).

Calcium antagonists

After repeated co-administration of Trileptal, the AUC values of felodipine were lowered by 28 %.
On the other hand, verapamil produced a decrease of 20 % in the plasma levels of MHD.

Other drugs interactions

Cimetidine, erythromycin and dextropropoxyphene had no effect on the pharmacokinetics of MHD, whereas viloxazine produced minor changes in the MHD plasma levels (about 10 % higher after repeated co-administration). Results with warfarin show no evidence of interaction with either single or repeated doses of Trileptal.

The interaction between oxcarbazepine and MAOIs is theoretically possible based on a structural relationship of oxcarbazepine to tricyclic antidepressants. Patients on tricyclic antidepressant therapy were included in clinical trials and no clinically relevant interactions have been observed. The combination of lithium and oxcarbazepine might cause enhanced neurotoxicity.

9. Pregnancy, lactation, females and males of reproductive potential

9.1 Pregnancy

Risk summary

Offspring of epileptic mothers are known to be more prone to developmental disorders, including malformations. Most frequently observed congenital malformations with the use of oxcarbazepine were ventricular septal defect, atrioventricular septal defect, cleft palate with cleft lip, Down's syndrome, dysplastic hip (both unilateral and bilateral), tuberous sclerosis and congenital malformation of the ear. It has been shown that in the offspring of women with epilepsy, the prevalence of malformation is two or three times greater than the rate of approximately 3 % in the general population. In the treated population, an increase in malformations has been noted with polytherapy, however, the extent to which the treatment and/or the illness is responsible has not been elucidated. Moreover, effective anti-epileptic therapy must not be interrupted, since the aggravation of the illness is detrimental to both the mother and the foetus.

Based on data in a North American pregnancy registry and EURAP registry (European and International Registry of Antiepileptic Drugs and Pregnancy), the prevelance of major congenital malformations, defined as a structural abnormality with surgical, medical, or cosmetic importance, diagnosed within 12 weeks of birth was 2.2% (95% CI 0.6 to 5.5%) and assessed after 1 year of birth was 2.9% (95% CI: 1.7 to 5.0) respectively, among mothers exposed to oxcarbazepine monotherapy in the first

trimester. When compared with pregnant women not exposed to any antiepileptic drugs the relative risk (RR) of congenital abnormality in pregnant women on oxcarbazepine is (RR) 2 (95% CI 0.5 to 7.4). Data on epileptic pregnant women receiving oxcarbazepine and unborn child exposed to oxcarbazepine during pregnancy remain inconclusive. However, risk of potential teratogenicity and neurodevelopment disorders cannot be completely excluded.

Data from an epidemiological study suggests an increased risk for infants of being born small for gestational age (potentially associated with fetal growth restriction) in pregnant women receiving antiepileptic drugs (including oxcarbazepine) during pregnancy compared to unexposed pregnant women with epilepsy.

Clinical considerations

Taking these data into consideration:

- If women receiving Trileptal become pregnant, or plan to become pregnant, or if the need to initiate treatment with Trileptal arises during pregnancy, the drug's potential benefits must be carefully weighed against the potential risk of fetal malformations. This is particularly important during the first three months of pregnancy.
- Minimum effective doses should be given.
- In women of childbearing age, whenever possible, it is recommended that Trileptal should be administered as monotherapy. The potential for congenital abnormalities in the offspring of women treated with combination therapies is greater than those receiving monotherapy.
- Patients should be counselled regarding the possibility of an increased risk of malformations and given the opportunity of antenatal screening.
- During pregnancy, an effective antiepileptic treatment should not be interrupted, since the aggravation of the illness is detrimental to both the mother and the fetus.

Monitoring and prevention

Antiepileptic drugs may contribute to folic acid deficiency, a possible contributory cause of fetal abnormality. Folic acid supplementation is recommended before and during pregnancy.

Due to physiological changes during pregnancy, plasma levels of the active metabolite of oxcarbazepine, the 10-monohydroxy derivative (MHD), may gradually decrease throughout pregnancy. It is recommended that clinical response should be monitored carefully in women receiving Trileptal treatment during pregnancy and determination of changes in MHD plasma concentrations should be considered to ensure that adequate seizure control is maintained throughout pregnancy (see section 4 Dosage regimen and administration and section 11 Clinical pharmacology).

Postpartum MHD plasma levels may also be considered for monitoring especially in the event that medication was increased during pregnancy.

In the newborn child

Bleeding disorders in the newborn caused by antiepileptic agents have been reported. As a precaution, vitamin K_1 should be administered as a preventive measure in the last few weeks of pregnancy and to the newborn.

Oxcarbazepine and its active metabolite (MHD) cross the placenta. Neonatal and maternal plasma MHD concentrations were similar in one case.

Animal data

Standard reproductive toxicity studies in rodents and rabbits revealed effects such as increases in the incidence of embryo-fetal mortality and/or some delay in antenatal and/or postnatal growth of the offspring at maternally toxic dose levels. There was an increase in rat fetal malformations in one of the eight embryo-fetal toxicity studies, which were conducted with either oxcarbazepine or MHD, at doses which also caused maternal toxicity.

9.2 Lactation

Risk summary

Oxcarbazepine and its active metabolite (MHD) are excreted in human breast milk. Limited data indicate that the breastfed infants' MHD plasma concentrations correspond up to 5 % of the maternal MHD plasma concentration. Although exposure appears to be low, a risk to the infant cannot be excluded. Therefore, a decision whether to continue breastfeeding while using oxcarbazepine should be considered based on the benefit of breastfeeding and the potential risk of side effects in the infant. If breastfed, the infant should be monitored for adverse effects such as drowsiness and poor weight gain.

9.3 Females and males of reproductive potential

Contraception

Women of child bearing potential should be advised to use highly effective contraception (preferably non-hormonal; e.g., intrauterine implants) while on treatment with Trileptal. Trileptal may result in a failure of the therapeutic effect of hormonal contraceptive drugs containing ethinylestradiol (EE) and levonorgestrel (LNG) (see section 6 Warnings and precautions and section 8 Interactions).

Infertility

There are no human data on fertility.

In rats, fertility in both sexes was unaffected by oxcarbazepine or MHD at oral doses up to 150 and 450 mg/kg/day, respectively. However, disruption of estrous cyclicity and reduced numbers of corpora lutea, implantations and live embryos were observed in female animals at the highest dose of MHD.

10. Overdosage

Isolated cases of overdose have been reported. The maximum dose taken was approximately 48,000 mg.

Signs and symptoms

Electrolyte and fluid balance conditions: hyponatremia

Eye disorders: diplopia, miosis, blurred vision

Gastrointestinal disorders: nausea, vomiting, hyperkinesia

General disorders and administration site conditions: fatigue

Investigations: respiratory rate depression, QTc prolongation

Nervous system disorders: drowsiness and somnolence, dizziness, ataxia, nystagmus, tremor, disturbances in coordination (coordination abnormal), convulsion, headache, coma, loss of consciousness, dyskinesia

Psychiatric disorders: aggression, agitation, confusional state

Vascular disorders: hypotension

Respiratory, thoracic and mediastinal disorders: dyspnoea

Management

There is no specific antidote. Symptomatic and supportive treatment should be administered as appropriate. Removal of the medicinal product by gastric lavage and/or inactivation by administering activated charcoal should be considered.

11. Clinical pharmacology

Pharmacotherapeutic group, ATC

Pharmacotherapeutic group: Antiepileptics, ATC code: N03A F02

Mechanism of action (MOA)

The pharmacological activity of Trileptal (oxcarbazepine) is primarily exerted through the metabolite (MHD) of oxcarbazepine (see section Pharmacokinetics (PK)-Biotransformation/Metabolism). The mechanism of action of oxcarbazepine and MHD is thought to be mainly based on blockade of voltage-sensitive sodium channels, thus resulting in stabilization of hyperexcited neural membranes, inhibition of repetitive neuronal firing, and diminishment of propagation of synaptic impulses. In addition, increased potassium conductance and modulation of high-voltage activated calcium channels may also contribute to the anticonvulsant effects. No significant interactions with brain neurotransmitter or modulator receptor sites were found.

Pharmacodynamics (PD)

Oxcarbazepine and its active metabolite (MHD), are potent and efficacious anticonvulsants in animals. They protected rodents against generalised tonic-clonic and, to a lesser degree, clonic seizures, and abolished or reduced the frequency of chronically recurring partial seizures in Rhesus monkeys with aluminum implants. No tolerance (i.e. attenuation of anticonvulsive activity) against tonic-clonic seizures was observed when mice and rats were treated daily for 5 days or 4 weeks, respectively, with oxcarbazepine or MHD.

Pharmacokinetics (PK)

Absorption

Following oral administration of Trileptal tablets, oxcarbazepine is completely absorbed and extensively metabolised to its pharmacologically active metabolite (10-monohydroxy derivative, MHD).

After single dose administration of 600 mg Trileptal tablets to healthy male volunteers under fasted conditions, the mean C_{max} value of MHD was 34 micromol/L, with a corresponding median t_{max} of 4.5 hours.

After single dose administration of 600 mg Trileptal oral suspension to healthy male volunteers under fasted conditions, the mean C_{max} value of MHD was 24.9 micromol/L, with a corresponding median t_{max} of 6 hours.

The tablet and suspension formulations of oxcarbazepine are bioequivalent since the geometric mean ratio (90% confidence interval) of single dose and steady state Cmax and AUC of MHD were in the range 0.85 to 1.06.

In a mass balance study in man, only 2 % of total radioactivity in plasma was due to unchanged oxcarbazepine, approximately 70 % was due to MHD, and the remainder attributable to minor secondary metabolites which were rapidly eliminated.

Food has no effect on the rate and extent of absorption of oxcarbazepine, therefore, Trileptal can be taken with or without food (see section 4 Dosage regimen and administration).

Distribution

The apparent volume of distribution of MHD is 49 litres.

Approximately 40 % of MHD, is bound to serum proteins, predominately to albumin. Binding was independent of the serum concentration within the therapeutically relevant range. Oxcarbazepine and MHD do not bind to alpha-1-acid glycoprotein.

Biotransformation/Metabolism

Oxcarbazepine is rapidly reduced by cytosolic enzymes in the liver to MHD, which is primarily responsible for the pharmacological effect of Trileptal. MHD is metabolised further by conjugation with glucuronic acid. Minor amounts (4 % of the dose) are oxidised to the pharmacologically inactive metabolite (10, 11-dihydroxy derivative, DHD).

Elimination

Oxcarbazepine is cleared from the body mostly in the form of metabolites which are predominantly excreted by the kidneys. More than 95 % of the dose appears in the urine, with less than 1 % as unchanged oxcarbazepine. Faecal excretion accounts for less than 4 % of the administered dose. Approximately 80 % of the dose is excreted in the urine either as glucuronides of MHD (49 %) or as unchanged MHD (27 %), whereas the inactive DHD accounts for approximately 3 % and conjugates of oxcarbazepine account for 13 % of the dose.

Oxcarbazepine is rapidly eliminated from the plasma with apparent half-life values between 1.3 and 2.3 hours. In contrast, the apparent plasma half-life of MHD averaged 9.3 ± 1.8 h.

Linearity/non-linearity

Steady-state plasma concentrations of MHD are reached within 2 to 3 days in patients when Trileptal is given twice a day. At steady-state, the pharmacokinetics of MHD are linear and show dose proportionality across the dose range of 300 to 2,400 mg/day.

Special populations

Hepatic impairment

The pharmacokinetics and metabolism of oxcarbazepine and MHD were evaluated in healthy volunteers and hepatically-impaired subjects after a single 900 mg oral dose. Mild to moderate hepatic impairment did not affect the pharmacokinetics of oxcarbazepine and MHD. Trileptal has not been studied in patients with severe hepatic impairment.

Renal impairment

There is a linear correlation between creatinine clearance and the renal clearance of MHD. When Trileptal is administered as a single 300 mg dose, in renally impaired patients (creatinine clearance < 30 mL/min), the elimination half-life of MHD is prolonged by 60-90 % (16 to 19 hours), with a two fold increase in AUC compared to adults with normal renal function (10 hours).

Pediatric patients (below 18 years)

Weight-adjusted MHD clearance decreases as age and weight increases approaching that of adults. The mean weight-adjusted clearance in children 4 to 12 years of age is approximately 40 % higher than that of adults. Therefore, MHD exposure in these children is expected to be about three-quarters than of adults when treated with a similar weight-adjusted dose. As weight increases, for patients 13 years of age and above, the weight-adjusted MHD clearance is expected to reach that of adults

Pregnancy

Due to physiological changes during pregnancy, MHD plasma levels may gradually decrease throughout pregnancy (see section 4 Dosage regimen and administration and section 9 Pregnancy, lactation, females and males of reproductive potential).

Geriatrics patients (65 years or above)

Following administration of single (300 mg) and multiple doses (600 mg/day) of Trileptal in elderly volunteers (60-82 years of age), the maximum plasma concentrations and AUC values of MHD were 30 to 60 % higher than in younger volunteers (18-32 years of age). Comparisons of creatinine clearances in young and elderly volunteers indicate that the difference was due to age-related reductions in creatinine clearance. No special dose recommendations are necessary because therapeutic doses are individually adjusted.

Gender

No gender related pharmacokinetic differences have been observed in children, adults, or the elderly.

12. Non-clinical safety data

Preclinical data indicated no special hazard for humans based on repeated dose toxicity, safety pharmacology and genotoxicity studies with oxcarbazepine and the pharmacologically active metabolite, monohydroxy derivative (MHD).

Evidence of nephrotoxicity was noted in repeated dose toxicity rat studies but not in dog or mice studies. As there are no reports of such changes in patients, the clinical relevance of this finding in rats remains unclear.

Immunotoxicity

Immunostimulatory tests in mice showed that MHD (and to a lesser extent oxcarbazepine) can induce delayed hypersensitivity.

Mutagenicity

Oxcarbazepine increased mutation frequencies in one Ames test *in vitro* in the absence of metabolic activation in one of five bacterial strains. Oxcarbazepine and MHD produced increases in chromosomal aberrations and/or polyploidy in the Chinese hamster ovary assay *in vitro* in the absence of metabolic activation. MHD was negative in the Ames test, and no mutagenic or clastogenic activity was found with either oxcarbazepine or MHD in V79 Chinese hamster cells *in vitro*. Oxcarbazepine and MHD were both negative for clastogenic or aneugenic effects (micronucleus formation) in an *in vivo* rat bone marrow assay.

Reproductive toxicity

For reproductive toxicity, see section 9 Pregnancy, lactation, females and males of reproductive potential.

Carcinogenicity

In the carcinogenicity studies, liver (rats and mice), testicular and female genital tract granular cell (rats) tumours were induced in treated animals. The occurrence of liver tumours was most likely a consequence of the induction of hepatic microsomal enzymes; an inductive effect which, although it cannot be excluded, is weak or absent in patients treated with Trileptal. Testicular tumours may have been induced by elevated luteinizing hormone concentrations. Due to the absence of such an increase in humans, these tumours are considered to be of no clinical relevance. A dose-related increase in the incidence of granular cell tumours of the female genital tract (cervix and vagina) was noted in the rat carcinogenicity study with MHD. These effects occurred at exposure levels comparable with the anticipated clinical exposure. The mechanism for the development of these tumours has not been elucidated. Thus, the clinical relevance of these tumours is unknown.

13. Pharmaceutical information

Incompatibilities

None known.

Special precautions for storage

Film-coated tablet

Do not store above 30°C. Store in the original package.
Trileptal should be kept out of the reach and sight of children.

Oral suspension

Store below 30°C. Store in the original package.
Use of Trileptal oral suspension within 7 weeks after first opening the bottles.
Trileptal should be kept out of the reach and sight of children.

Shelf-life

The expiry date is indicated on the packaging.

Instructions for use and handling

Before taking Trileptal oral suspension, the bottle should be shaken well and the dose prepared immediately afterwards. The prescribed amount of oral suspension should be withdrawn from the bottle using the oral syringe supplied. The amount should be rounded to the nearest 0.1 mL when using the 1 mL syringe (supplied with the bottle containing 100 mL for younger children). Trileptal oral suspension may be swallowed directly from the syringe or can be mixed in a small glass of water just prior to administration. After each use, the bottle should be closed and the outside of the syringe wiped with a dry, clean tissue.

Nature and content of container

Trileptal 300 mg film-coated tablet, box of 5 blisters @ 10 tablets
Reg. No. DKI0167502717A1

Trileptal 60 mg/mL oral suspension, box of 1 bottle @ 100 mL
Reg. No. DKI1664100633A1

HARUS DENGAN RESEP DOKTER

To be dispensed only on the prescription of a physician

Trileptal 300 mg film-coated tablet
Manufactured by Novartis Farma S.p.A., Torre Annunziata, Italy for Novartis Pharma AG, Basel, Switzerland

Trileptal 60 mg/mL oral suspension
Manufactured by Delpharm Huningue S.A.S., Huningue, France for Novartis Pharma AG, Basel, Switzerland

Imported by PT Novartis Indonesia, Jakarta, Indonesia.

Leaflet based on CDS v3.2 25-Nov-2024

TRILEPTAL® (oxcarbazepin)

300 mg tablet salut selaput
60 mg/mL suspensi oral

Informasi Produk Untuk Pasien

DISETUJUI OLEH BPOM: 10/02/2026 ID: EREG10000512500220

Bacalah brosur ini dengan saksama sebelum Anda mengonsumsi obat ini

Mohon simpan brosur ini. Anda mungkin akan membutuhkannya untuk dibaca kembali.

Obat ini diresepkan hanya untuk Anda. Jangan gunakan obat ini untuk penyakit lain; jangan berikan obat ini kepada orang lain karena dapat membahayakan meskipun gejala penyakitnya serupa dengan gejala penyakit Anda.

Jika terjadi efek samping yang berat, atau Anda mengalami efek samping yang tidak disebutkan dalam brosur ini, mohon informasikan kepada dokter, apoteker atau tenaga kesehatan Anda.

Jika Anda memiliki pertanyaan lebih lanjut, mohon tanyakan kepada dokter, apoteker atau tenaga kesehatan Anda.

Apa isi brosur ini

1 Apakah Trileptal® itu dan apa kegunaannya

Apakah Trileptal itu

Trileptal termasuk dalam golongan obat antikonvulsan atau antiepileptik (obat-obatan untuk terapi epilepsi).

Obat antiepileptik seperti Trileptal merupakan obat terapi standar untuk epilepsi.

Apakah kegunaan Trileptal

Epilepsi adalah gangguan pada otak yang menyebabkan terjadinya kejang dan konvulsi secara berulang. Terjadinya kejang disebabkan karena terjadinya gangguan sementara dari aktivitas listrik pada otak. Secara normal, sel-sel otak berkoordinasi dengan gerakan tubuh dengan cara mengirimkan sinyal melalui saraf otak ke otot secara teratur. Pada penderita epilepsi, sel-sel otak mengirimkan terlalu banyak sinyal ke otot secara tidak teratur, sehingga menyebabkan aktivitas otot menjadi tidak terkoordinasi yang disebut sebagai kejang epileptik. Trileptal bekerja dengan cara mengontrol aktivitas sel-sel saraf otak sehingga dapat menekan atau mengurangi frekuensi terjadinya kejang.

Terdapat dua kelompok utama dari kejang epileptik: umum dan parsial.

Kejang umum melibatkan area otak secara luas, dapat menyebabkan kehilangan kesadaran dan berdampak ke seluruh tubuh. Terdapat dua tipe utama dari kejang umum: kejang tonik-klonik (*grand mal*) and kejang absans (*petit mal*).

Kejang parsial melibatkan area otak secara terbatas (contohnya: bagian fokal), akan tetapi dapat menyebar ke seluruh area otak dan dapat menyebabkan kejang umum tonik-klonik sekunder. Terdapat dua tipe utama dari kejang parsial: sederhana dan kompleks. Pada kejang parsial sederhana, pasien dapat tetap sadar, sedangkan pada kejang parsial kompleks, kesadaran pasien akan terganggu.

Trileptal digunakan untuk pengobatan kejang parsial (sederhana, kompleks dan kejang umum tonik-klinik sekunder) and kejang umum tonik-klonik. Trileptal digunakan untuk pasien dewasa dan pasien anak usia lebih dari lima tahun.

Biasanya, dokter akan menetapkan obat yang tepat untuk pasien epilepsi, akan tetapi, pada penyakit epilepsi yang berat, kombinasi dari dua atau lebih obat dapat diperlukan untuk mengkontrol kejang. Trileptal dapat digunakan secara tunggal (monoterapi) atau kombinasi dengan antiepileptik lainnya.

Pemantauan selama pengobatan menggunakan Trileptal

Pada saat sebelum dan selama pengobatan menggunakan Trileptal, dokter Anda akan melakukan tes darah untuk menetapkan dosis yang tepat untuk Anda. Dokter Anda akan menginformasikan kepada Anda mengenai kapan Anda dapat menjalani tes tersebut.

2 Apa yang harus Anda ketahui sebelum dan selama mengonsumsi Trileptal

Mohon agar mengikuti petunjuk dokter dengan saksama. Petunjuk dokter tersebut mungkin dapat berbeda dengan informasi umum yang terdapat dalam brosur ini.

Risiko terjadinya gangguan kulit yang serius pada pasien keturunan *Han Chinese* atau *Thai* yang berhubungan dengan oxcarbazepin, karbamazepin atau senyawa lain yang mirip secara stuktur kimia dapat diprediksi dengan cara melakukan tes darah pada pasien-pasien tersebut.

Dokter Anda akan memberikan saran kepada Anda apakah tes darah perlu dilakukan sebelum Anda menggunakan Trileptal.

Mohon untuk tidak mengonsumsi Trileptal

- Jika Anda **alergi (hipersensitif)** terhadap oxcarbazepin (zat aktif dari Trileptal) atau zat tambahan lain dari Trileptal yang tertera pada bagian akhir brosur ini.
- Jika Anda memiliki *atrioventricular block* (AV blok atau ganguan pada jalur penghantaran listrik pada jantung).
- Jika Anda memiliki sejarah depresi sumsum tulang atau *acute intermittent porphyria* (gangguan produksi heme)
- Jika Anda memiliki gangguan fungsi ginjal

Jika hal ini terjadi pada Anda, **mohon informasikan kepada dokter Anda sebelum Anda mengonsumsi Trileptal.** Jika Anda kemungkinan mengalami alergi, mohon untuk meminta saran kepada dokter Anda.

Peringatan dan perhatian

- Jika Anda pernah mengalami **sensitivitas yang tidak biasa** (ruam atau tanda-tanda alergi yang lain) terhadap karbamazepin atau obat-obat yang lain. Jika Anda alergi terhadap karbamazepin, sekitar 25 % kemungkinan Anda juga dapat mengalami reaksi alergi terhadap oxcarbazepin (Trileptal).
- Jika Anda memiliki **penyakit ginjal**.
- Jika Anda memiliki **penyakit hati serius**.
- Jika Anda sedang menggunakan **diuretik** (obat-obat yang digunakan untuk mengurangi garam dan air dengan meningkatkan produksi urin).
- Jika Anda memiliki **penyakit jantung**, nafas pendek dan/atau pembengkakan pada kaki atau lengan karena timbunan cairan.
- Jika hasil tes darah menunjukan bahwa **kadar natrium dalam darah Anda rendah.**
- Jika Anda sedang menggunakan obat-obat lain **(Lihat 'Penggunaan obat lain').**
- Jika Anda wanita yang sedang menggunakan **kontrasepsi hormonal** (contoh: pil KB), Trileptal dapat menyebabkan kontrasepsi tersebut tidak efektif. Oleh karena itu, Anda disarankan untuk menggunakan metode kontrasepsi non-hormonal (contoh: implan intrauterin) jika Anda sedang mengonsumsi Trileptal. Hal ini dapat membantu Anda mencegah kehamilan yang tidak diinginkan. Mohon informasikan kepada dokter Anda jika Anda mengalami pendarahan atau flek pada vagina secara tidak biasa. Jika Anda memiliki pertanyaan mengenai hal ini, mohon tanyakan kepada dokter atau tenaga profesional kesehatan Anda.

Jika hal-hal diatas terjadi pada Anda, **mohon informasikan kepada dokter Anda sebelum Anda mengonsumsi** Trileptal.

Jika Anda mengalami gejala-gejala dibawah ini setelah memulai pengobatan dengan Trileptal, mohon segera informasikan kepada dokter Anda atau pergi ke bagian Unit Gawat Darurat di rumah sakit terdekat:

- Jika terjadi **reaksi alergi** seperti pembengkakan pada bibir, kelopak mata, wajah, tenggorokan, mulut atau gangguan pernafasan mendadak, demam dengan kelenjar yang membengkak (pembengkakan kelenjar getah bening), ruam atau kulit melepuh **(Lihat 'Efek samping yang mungkin terjadi')**.
- **Jika Anda mengalami reaksi kulit yang serius** seperti ruam, kulit kemerahan, bibir mata atau mulut melepuh, kulit mengelupas yang disertai dengan demam **(Lihat 'Efek samping yang mungkin terjadi')**. Reaksi ini kemungkinan lebih sering terjadi pada pasien di negara-negara Asia (contoh: Taiwan, Malaysia dan Filipina) dan pada pasien keturunan Chinese.
- Jika Anda mengalami **peningkatan frekuensi kejang**. Hal ini dapat terjadi **terutama pada pasien anak**, dan dapat pula terjadi pada pasien dewasa.

- Jika Anda merasakan gejala **hepatitis**, seperti *jaundice* (kulit dan mata berwarna kuning).
- Jika Anda merasakan gejala seperti **gangguan darah,** seperti kelelahan, nafas pendek ketika berolahraga, pucat, sakit kepala, menggigil, pusing, infeksi yang sering disertai demam, sakit tenggorokan, lesi pada mulut, mudah mengalami pendarahan atau memar, hidung berdarah, tanda kemerahan atau keunguan atau bercak yang tidak wajar pada kulit.
- Jika Anda memiliki keinginan untuk **menyakiti atau membunuh diri sendiri**. Sebagian kecil dari pasien yang menggunakan pengobatan dengan antiepileptik dapat mengalami gangguan perilaku ini.
- Jika Anda mengalami **detak jantung yang cepat atau lambat secara tidak biasa**

Jangan menghentikan pengobatan dengan Trileptal tanpa terlebih dahulu berkonsultasi dengan dokter Anda. Untuk menghindari perburukan kejang secara mendadak, mohon untuk tidak menghentikan penggunaan obat secara tiba-tiba.

Penggunaan obat lain (interaksi dengan obat lain termasuk vaksin dan produk biologi)

Sebelum mengonsumsi Trileptal, beritahukan kepada dokter atau apoteker Anda jika Anda sedang ataupun baru saja mengonsumsi obat-obat lain, termasuk obat yang didapatkan tanpa resep dokter, karena potensi terjadi interaksi dengan Trileptal.

Hal ini berlaku terutama untuk obat-obat berikut:

- Kontrasepsi hormonal (contoh: pil KB) **(Lihat 'Peringatan dan perhatian').**
- Obat-obatan antiepileptik lain (contoh: karbamazepin, fenobarbital, fenitoin dan rifampicin).
- Felodipin (sejenis obat yang digunakan untuk pengobatan tekanan darah tinggi).
- Obat-obatan yang digunakan untuk mengurangi kadar natrium dalam darah, seperti: diuretik (obat-obat yang digunakan untuk mengurangi garam dan air dengan meningkatkan produksi urin).
- Obat-obatan yang digunakan untuk mengkontrol sistem imun tubuh (contoh: ciclosporin, tacrolimus).

Mengonsumsi Trileptal dengan makanan dan minuman

Trileptal dapat dikonsumsi dengan atau tanpa makanan. Alkohol dapat meningkatan efek sedatif dari Trileptal. Mohon untuk menghindari penggunaan alkohol sebisa mungkin dan minta saran kepada dokter Anda.

Anak dan remaja (dibawah usia 18 tahun)

Trileptal dapat dikonsumsi oleh pasien anak usia 5 tahun keatas, sesuai dengan petunjuk dokter. Pada pasien anak, dokter Anda kemungkinan akan menyarankan pemantauan fungsi tiroid pada saat sebelum dan selama menjalani terapi.

Pasien usia lanjut (usia 65 tahun keatas)

Trileptal dapat dikonsumsi oleh pasien diatas usia 65 tahun, sesuai dengan petunjuk dokter.

Kehamilan

Mohon informasikan kepada dokter Anda jika Anda sedang hamil, mengira Anda mungkin hamil atau berencana untuk hamil.

Sangatlah penting untuk mengontrol kejang epileptik selama kehamilan. Akan tetapi, terdapat kemungkinan risiko terhadap bayi dalam kandungan jika Anda mengonsumsi obat antiepileptik selama kehamilan.

Cacat lahir
Belum ada studi yang menunjukkan peningkatan risiko cacat lahir terkait dengan penggunaan oxcarbazepine selama kehamilan, namun risiko cacat lahir untuk bayi yang belum lahir tidak dapat sepenuhnya dikesampingkan.

Gangguan perkembangan saraf
Beberapa studi menunjukkan bahwa paparan oxcarbazepine di dalam rahim berdampak negatif pada perkembangan fungsi otak (*neurodevelopment*) pada anak-anak, sementara studi lain belum menemukan efek seperti itu. Kemungkinan efek pada perkembangan saraf tidak dapat dikesampingkan.

Temuan dari studi besar epidemiologi yang diterbitkan telah menunjukkan bahwa penggunaan oxcarbazepine dapat memengaruhi pertumbuhan bayi Anda yang belum lahir selama kehamilan.

Dokter Anda akan menjelaskan kepada Anda mengenai manfaat dan kemungkinan potensi risiko yang akan terjadi, serta akan membantu Anda dalan memutuskan apakah Anda perlu mengonsumsi Trileptal.

Mohon untuk tidak menghentikan penggunaan Trileptal selama kehamilan tanpa terlebih dahulu berkonsultasi dengan dokter Anda.

Mohon minta saran kepada dokter atau apoteker Anda sebelum Anda menggunakan obat apapun selama masa kehamilan.

Menyusui

Mohon minta saran kepada dokter Anda sebelum Anda menggunakan obat apapun selama masa menyusui. Zat aktif yang terkandung dalam obat Trileptal dapat melewati air susu ibu. Meskipun data yang tersedia menunjukkan bahwa jumlah Trileptal yang masuk ke bayi yang disusui rendah, risiko efek samping pada bayi tidak dapat dikesampingkan. Dokter Anda akan mendiskusikan dengan Anda manfaat dan potensi risiko menyusui saat mengonsumsi Trileptal. Jika Anda sedang menyusui saat mengonsumsi Trileptal dan menurut Anda bayi Anda mengalami efek samping seperti kantuk berlebihan atau kenaikan berat badan yang buruk, segera beri tahu dokter Anda.

Wanita yang berpotensi untuk melahirkan anak

Jika Anda adalah wanita yang sedang menggunakan kontrasepsi hormonal (contoh: pil KB), Trileptal dapat menyebabkan kontrasepsi tersebut tidak efektif. Oleh karena itu, Anda disarankan untuk menggunakan metode kontrasepsi non-hormonal (contoh: implan intrauterin) jika Anda sedang mengonsumsi Trileptal.

Mengemudikan kendaraan dan menggunakan mesin

Sangatlah penting untuk membicarakan kepada dokter Anda jika Anda mengemudikan kendaraan atau mengoperasikan mesin, karena Trileptal dapat menyebabkan Anda mengantuk atau pusing, pandangan kabur, pandangan ganda, kurangnya koordinasi otot atau tingkat kesadaran yang memburuk, terutama pada saat memulai terapi atau melakukan peningkatan dosis.

3 Bagaimana cara mengonsumsi Trileptal

Mohon untuk selalu mengonsumsi obat ini sesuai dengan petunjuk dokter Anda, bahkan jika petunjuk tersebut berbeda dengan apa yang tertulis pada brosur ini.

Mohon untuk tidak melampaui batas penggunaan dosis yang direkomendasikan.

Jika Anda sedang mengonsumsi Trileptal, mohon untuk **tidak menghentikan penggunaannya secara tiba-tiba** tanpa berkonsultasi terlebih dahulu dengan dokter Anda. Dokter Anda akan menyarankan Anda mengenai kapan dan pada kondisi apa Anda diperbolehkan menghentikan terapi (**Lihat 'Peringatan dan perhatian'**).

Berapa dosis Trileptal yang harus Anda konsumsi

Mohon untuk mengonsumsi obat sesuai petunjuk dokter atau apoteker Anda.

Suspensi oral: Dosis yang diresepkan untuk Anda harus diberikan dalam mililiter (mL) dan bukan dalam miligram (mg). Hal ini penting karena *syringe* oral yang digunakan untuk menarik dosis obat dari botolnya adalah dalam satuan mL. Jika resep Anda tertulis dalam satuan mg, jangan konsumsi obat Anda dan segera hubungi dokter atau apoteker Anda untuk meminta saran.

Dosis untuk pasien dewasa

Trileptal sebaiknya dikonsumsi dua kali sehari, diwaktu yang sama setiap hari, kecuali dokter menyarankan berbeda. Konsumsi Trileptal pada saat yang sama setiap hari akan memberikan efek optimal dalam mengontrol epilepsi. Hal ini juga akan membantu Anda untuk mengingat waktu konsumsi Trileptal setiap hari.

Dosis awal adalah 600 mg (10 mL suspensi oral) per hari, yang diberikan dalam dua dosis terbagi.

Gunakan dosis 300 mg tablet dua kali sehari atau 1 dosis 5 mL suspensi oral (300 mg) dua kali sehari. Dosis ini dapat ditingkatkan secara bertahap, jika diperlukan, sampai dengan tercapainya

hasil yang optimal. Dosis pemeliharaan biasanya diantara 600 sampai dengan 2400 mg (10 dan 40 mL suspensi oral) per hari.

Dosis Trileptal yang digunakan secara kombinasi dengan antiepileptik lain adalah sama dengan dosis diatas.

Dosis awal pada pasien dengan gangguan fungsi ginjal adalah setengah dari dosis awal pada pasien normal.

Dosis untuk pasien anak

Dosis untuk pasien anak dihitung oleh dokter berdasarkan berat badan. Dosis awal 8 sampai 10 mg per kg berat badan per hari yang diberikan dalam dua dosis terbagi. Misalnya, pasien anak dengan berat badan 30 kg menggunakan dosis awal 150 mg (1 dosis 150 mg atau 2.5 mL suspensi oral) dua kali sehari. Jika diperlukan, dosis ini dapat ditingkatkan secara bertahap sampai dengan tercapainya hasil yang optimal. Dosis maksimum untuk anak adalah 60 mg per kg berat badan per hari.

Bagaimana cara mengonsumsi Trileptal

Untuk tablet salut selaput

Telanlah tablet dengan sedikit air. Jika diperlukan, tablet dapat dibelah dua untuk membantu memudahkan dalam menelan. Untuk pasien anak yang belum bisa menelan tablet, tersedia bentuk sediaan oral suspensi. Mintalah saran kepada dokter atau apoteker Anda.

Untuk suspensi oral

Kocoklah botol sebelum digunakan. Siapkan dosis suspensi oral dengan segera. Obat dapat langsung diminum melalui *syringe* oral atau dapat dicampurkan dalam segelas kecil air sebelum diminum. Aduk dan minumlah larutan obat dengan segera (**Lihat 'Instruksi cara penggunaan'** dibawah).

INSTRUKSI CARA PENGGUNAAN

Trileptal® Suspensi oral tersedia dalam kemasan:
100 mL dengan *syringe* 1 mL

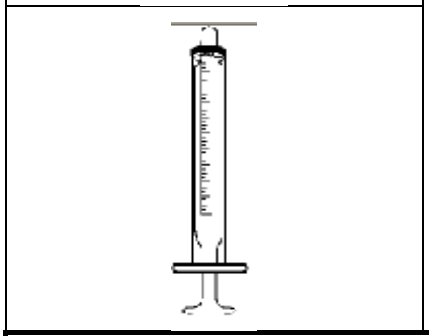
Mohon untuk membaca instruksi ini dengan hati-hati sehingga Anda dapat mengetahui bagaimana cara menyediakan obat ini dengan benar.

Sistem Penyediaan Obat

Terdapat 3 bagian dari sistem penyediaan obat:

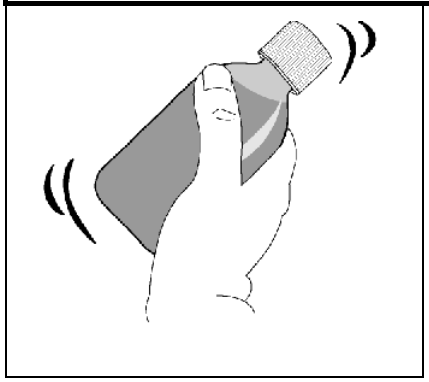
1. **Adapter plastik** yang harus Anda tekan kearah leher botol pada saat pertama kali Anda membuka botol.

   Adapter harus selalu berada pada botol.
2. Botol yang berisi obat, dan disertai dengan penutup. Mohon untuk selalu meletakkan kembali penutupnya setelah botol digunakan.



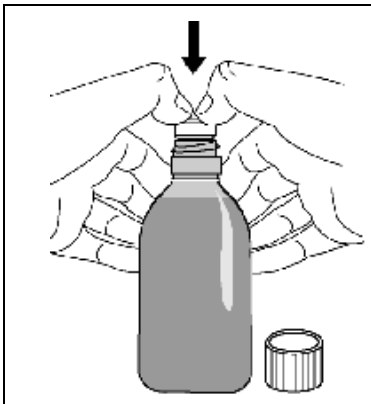
3. ***Syringe* oral** yang dapat dilekatkan dengan adapter plastik untuk menarik dosis obat dari dalam botolnya.

Penyiapan botol



1. Kocok botol obat selama **tidak kurang dari 10 detik.**
2. Lepaskan penutup botol dengan cara menekan **kuat** kebawah dan memutarnya secara berlawanan arah jarum jam (seperti gambar yang terlihat pada bagian atas penutup).

Catatan: Jagalah agar penutup tetap dalam kondisi baik supaya tetap dapat digunakan untuk menutup botol setelah obat digunakan.



3. Peganglah botol yang telah terbuka secara tegak di atas meja dan dorong adapter plastik pas ke dalam leher botol sedalam mungkin.
4. Pasanglah penutup botol untuk memastikan bahwa adapter telah sepenuhnya terdorong ke leher botol

Catatan: Anda mungkin tidak dapat mendorong adapter sepenuhnya ke bawah, akan tetapi adapter tersebut akan terdorong lebih dalam ketika Anda memutar kembali penutup botol tersebut.

5. Botol telah siap pakai menggunakan *syringe*. Adapter harus tetap berada pada botol.

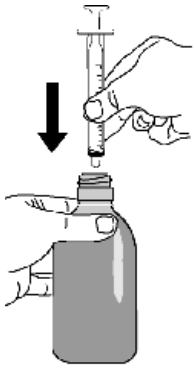
Untuk dapat menyediakan dosis obat, mohon mengikuti instruksi cara **penggunaan obat.**

Penggunaan obat

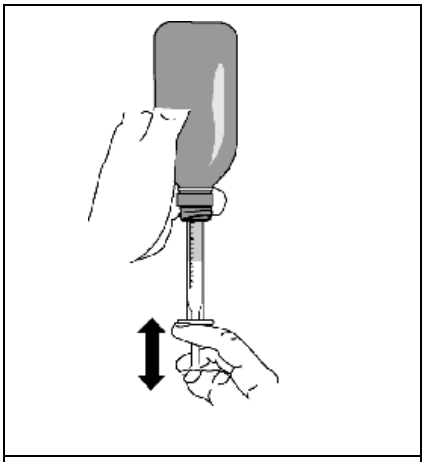
Obat dapat langsung diminum melalui *syringe* oral atau dapat dicampurkan dalam segelas kecil air.

1. Kocoklah botol dengan benar. Siapkan dosis obat dengan segera.
2. Dorong dan putar penutup botol untuk membuka botolnya.

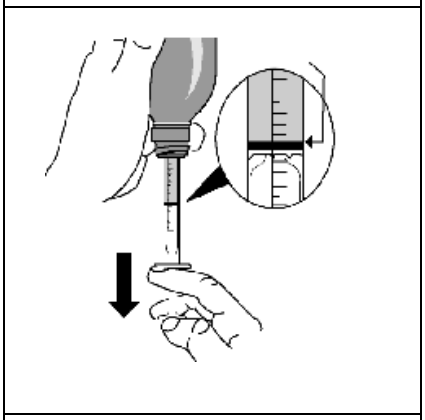
(Catatan: Mohon untuk selalu meletakkan kembali penutup botol setelah obat selesai digunakan)



3. Periksalah *plunger* apakah telah sepenuhnya masuk ke dalam laras *syringe* oral.
4. Jagalah botol agar tetap tegak dan masukkan *syringe* oral ke dalam adapter plastik dengan kuat.

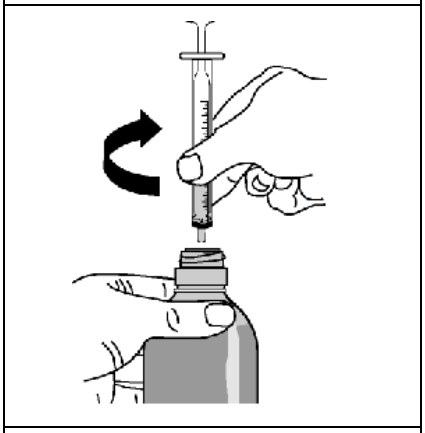


5. Peganglah *syringe* oral pada tempatnya dan putar balik botol dengan hati-hati.
6. Tarik *plunger* kebawah secara perlahan sehingga *syringe* dapat terisi dengan obat. Dorong kembali *plunger* tersebut untuk menghilangkan gelembung besar yang terjebak di dalam *syringe* oral.

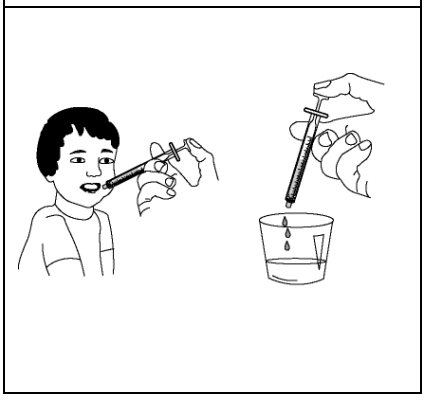


7. **Mengeluarkan dosis obat**: tarik *plunger* perlahan-lahan ke bawah sampai mencapai tepi atas cincin hitam yang menunjukkan dosis yang ditentukan.

Catatan: Jika dosis yang ditetapkan lebih besar dari yang dapat terukur dalam *syringe*, Anda harus mengisi kembali *syringe* oral tersebut untuk mendapatkan dosis yang utuh.



8. Putar baliklah botol dengan hati-hati. Keluarkan *syringe* oral dengan cara memutar pelan *syringe* tersebut agar terlepas dari adapter plastik. Adapter plastik harus tetap berada pada botol.



9. Obat dapat langsung diminum melalui *syringe* oral (pasien harus dalam posisi duduk kemudian *plunger* didorong perlahan untuk memudahkan pasien menelan obat). Cara lainnya, obat dapat dicampurkan dalam segelas kecil air sebelum diminum. Aduk dan minumlah larutan obat dengan segera.
10. Letakkan kembali penutup botol setelah obat selesai digunakan.
11. **Cara membersihkan:** Setelah digunakan, bersihkan bagian luar *syringe* menggunakan tisu yang kering dan bersih.

Kapan dan berapa lama Anda harus mengonsumsi Trileptal

Dokter Anda akan menginformasikan kepada Anda mengenai berapa lama Anda/anak Anda harus mengonsumsi Trileptal. Durasi pengobatan ditentukan berdasarkan tipe kejang yang Anda/anak Anda alami; pengobatan secara berkelanjutan selama beberapa tahun mungkin diperlukan untuk mengontrol kejang. Mohon untuk tidak mengubah dosis atau menghentikan pengobatan tanpa terlebih dahulu berkonsultasi dengan dokter Anda.

Jika Anda mengonsumsi Trileptal lebih dari yang seharusnya

Jika Anda mengonsumsi dosis Trileptal lebih besar dari yang diresepkan oleh dokter Anda, mohon segera menghubungi rumah sakit terdekat atau dokter Anda.

Jika Anda lupa mengonsumsi Trileptal

Jika Anda lupa mengonsumsi satu dosis, mohon agar sesegera mungkin mengonsumsi dosis tersebut setelah Anda ingat. Akan tetapi, jika waktu konsumsi dosis selanjutnya telah tiba, mohon agar langsung mengonsumsi dosis selanjutnya tanpa perlu mengganti dosis yang terlewat. Untuk konsumsi dosis di hari berikutnya, mohon untuk konsumsi dosis seperti biasa. Jangan mengonsumsi dua dosis pada saat yang sama.

Jika Anda tidak yakin atau lupa mengonsumsi beberapa dosis obat, mohon segera menghubungi dokter Anda.

Jika Anda berhenti mengonsumsi Trileptal

Penghentian pengobatan menggunakan Trileptal dapat memperburuk kejang Anda. Mohon untuk tidak menghentikan pengobatan terkecuali disarankan oleh dokter Anda (**Lihat ‘Peringatan dan perhatian’**).

4 Efek samping yang mungkin terjadi

Seperti pada penggunaan obat-obat lain, selain memberikan efikasi terapi, Trileptal juga dapat menyebabkan efek samping.

Beberapa efek samping yang dapat menjadi serius

- Pembengkakan pada bibir, kelopak mata, wajah, tenggorokan atau mulut yang disertai dengan kesulitan bernafas, berbicara atau menelan (tanda-tanda reaksi anafilaksis dan angioedema) atau tanda-tanda reaksi hipersensitivitas seperti ruam kulit, demam, nyeri otot dan persendian.
- Kulit dan/atau membran mukosa bibir, mata, mulut, saluran hidung atau genital melepuh secara hebat (tanda-tanda reaksi alergi serius).
- Kelelahan, nafas pendek ketika berolahraga, pucat, sakit kepala, menggigil, pusing, infeksi yang sering disertai demam, sakit tenggorokan, lesi pada mulut, mudah mengalami pendarahan atau memar, hidung berdarah, tanda kemerahan atau keunguan atau bercak yang tidak wajar pada kulit (tanda-tanda penurunan jumlah trombosit darah atau penurunan jumlah sel darah).

- Ruam bercak merah terutama pada wajah, yang disertai dengan rasa penat, demam, mual dan kehilangan nafsu makan (tanda-tanda sistemik lupus eritematosus).
- Lesu, kebingungan, kejang pada otot atau perburukan kejang yang bermakna (gejala yang mungkin berhubungan dengan kadar natrium yang rendah dalam darah) **(Lihat 'Peringatan dan perhatian').**
- Gejala seperti flu disertai *jaundice* (tanda-tanda hepatitis).
- Nyeri hebat pada bagian perut, muntah, kehilangan nafsu makan (tanda-tanda pankreatitis).
- Kenaikan berat badan, kelelahan, rambut rontok, kelemahan otot, rasa kedinginan (tanda-tanda menurunnya aktivitas kelenjar tiroid).

Jika Anda mengalami hal diatas, **segera beritahukan dokter Anda**.

Beberapa efek samping yang sangat sering terjadi

Beberapa efek samping dibawah ini dapat terjadi pada lebih dari 1 pasien dari setiap 10 pasien.

- Kelelahan
- Sakit kepala
- Pusing
- Mengantuk
- Mual
- Muntah
- Pandangan ganda.

Jika Anda mengalami hal diatas secara berat, **mohon beritahukan dokter Anda.**

Beberapa efek samping yang sering terjadi

Beberapa efek samping dibawah ini dapat terjadi pada 1 sampai 10 pasien dari setiap 100 pasien

- Gemetar
- Masalah dengan koordinasi tubuh
- Gangguan pada mata
- Rasa cemas dan gelisah
- Rasa depresi
- Suasana hati (*mood)* yang berubah-ubah
- Rasa lemah
- Gangguan memori
- Konsentrasi yang terganggu
- Apati
- Perasaan yang bergejok (agitasi)
- Kebingungan
- Pandangan kabur

- Konstipasi
- Diare
- Nyeri perut
- Jerawat
- Rambut rontok
- Gangguan keseimbangan.
- Kadar natrium dalam darah rendah
- Ruam kulit
- Peningkatan berat badan

Jika Anda mengalami hal diatas secara berat, **mohon beritahukan dokter Anda**.

Beberapa efek samping yang sangat jarang terjadi

Beberapa efek samping dibawah ini dapat terjadi pada kurang dari 1 parien dari setiap 10,000 pasien

- Defisiensi sel darah dikarenakan gangguan pada sumsus tulang seperti (depresi sumsum tulang, agranulositosis, anemia aplastik, pansitopenia, neutropenia, trombositopenia).
- Hipersensitifitas dan gangguan sistem imun.
- Kekurangan kadar natrium yang ditunjukan dengan tanda-tanda seperti kejang, kebingungan, kurang kesadaran, gangguan penglihatan, mual, dan muntah
- Defisiensi vitamin B9 (asam folat). Beberapa tanda-tanda defisiensi vitamin B9: diare, rasa depresi dan tanda-tanda penurunan jumlah sel darah **(Lihat sub-bagian 'Beberapa efek samping yang dapat menjadi serius')**.
- Kekurangan hormon tiroid
- Gangguan pada sistem saraf seperti: rasa kantuk, sakit kepala dan pusing
- Gangguan detak jantung (aritmia) dan ganguan penghantaran listrik pada jantung (AV blok)
- Pankreatitis dan/atau peningkatan kadar lipase dan amilase
- Angioedema, sindroma *Stevens-Johnson*, sindroma *Lyell*, multiform eritema
- *Systemic Lupus Eruthematosus* (Lupus)
- Tekanan darah tinggi

Beberapa efek samping lainnya

Beberapa efek samping yang frekuensi kejadiannya tidak diketahui.

- Gangguan berbicara
- Gangguan pada tulang termasuk osteopenia dan osteoporosis (penipisan tulang) dan patah tulang pada pasien yang menjalani pengobatan menggunakan Trileptal dalam jangka waktu yang lama.

Jika Anda mengalami hal diatas secara berat, **mohon beritahukan dokter Anda.**

Jika Anda mengetahui adanya efek samping lain yang tidak disebutkan dalam brosur ini, **mohon beritahukan kepada dokter atau apoteker Anda**.

Pelaporan efek samping

Apabila ada keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat, konsultasikan ke dokter, apoteker, atau perawat. Anda dapat juga melaporkan keluhan efek samping atau kondisi tidak nyaman tersebut secara langsung ke Industri Farmasi melalui kontak berikut:

Novartis Indonesia
Website: www.novartis.com/report

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

5 Cara penyimpanan Trileptal

- Jauhkan obat ini dari jangkauan anak-anak.
- Mohon untuk tidak mengonsumsi obat setelah tanggal kedaluwarsa yang tercantum pada dus obat.
- Simpan Trileptal dalam kemasan aslinya.
- Simpan Trileptal tablet salut selaput pada suhu tidak lebih dari 30°C.
- Simpan Trileptal suspensi oral pada suhu di bawah 30°C.
- Trileptal suspensi oral: Gunakan selama maksimal 7 minggu setelah botol dibuka.
- Mohon tidak menggunakan obat jika kemasannya rusak atau menunjukkan adanya cacat.
- Trileptal tablet salut selaput: Kembalikan tablet yang tidak terpakai ke apotek Anda agar dapat dimusnahkan dengan aman.
- Trileptal suspensi oral: Setelah 7 minggu, kembalikan suspensi oral yang tidak terpakai ke apotek Anda agar dapat dimusnahkan dengan aman.

6 Informasi lebih lanjut

Apakah kandungan Trileptal

- **Zat aktif** dari Trileptal adalah oxcarbazepin.
- **Zat tambahan** lainnya adalah:

Tablet salut selaput
Inti tablet: silika, koloidal anhidrat; mikrokristaline selulosa; hipromelosa; krospovidon; magnesium stearat;
Salut Tablet
Hipromelosa, makrogol 8000, iron oksida kuning (E 172), talk, titanium dioksida (E 171).

Suspensi oral
Air terpurifikasi, larutan sorbitol, propilen glikol, selulosa mikrokristalin dan natrium karmelosa, asam askorbat, aroma plum-lemon kuning 39K 020, metilparahidroksibenzoat, makrogol stearat, etanol, asam sorbat, natrium sakarin, propil parahidroksibenzoat.

Bagaimana bentuk dan isi Trileptal

Trileptal tersedia dalam bentuk sediaan tablet salut selaput dan suspensi oral.

Trileptal tablet salut selaput: Setiap tablet mengandung 300 mg zat aktif oxcarbazepin.
Tablet berwarna kuning, ovaloid, agak *biconvex*, terdapat garis tengah di kedua sisinya, dicetak dengan huruf "TE", garis bagi, "TE" terbalik pada satu sisi dan "CG", garis bagi, "CG" terbalik pada sisi lainnya. Garis tengah pada Trileptal 300 mg tablet salut selaput untuk membagi tablet menjadi dosis yang sama.

Trileptal suspensi oral: Trileptal suspensi oral berwarna putih sampai agak coklat atau agak merah. Perubahan warna suspensi oral menjadi agak coklat kemerahan adalah normal dan tidak berpengaruh terhadap mutu produk.

Setiap mL suspensi oral mengandung 60 mg zat aktif oxcarbazepin.

Kemasan

Trileptal 300 mg tablet salut selaput
Dus, 5 blister @ 10 tablet salut selaput No. Reg. DKI0167502717A1

Trileptal 60 mg/mL suspensi oral
Dus, 1 botol @ 100 mL No. Reg. DKI1664100633A1

HARUS DENGAN RESEP DOKTER

Pemegang Nomor Ijin Edar

PT Novartis Indonesia.

Pabrik pembuat
Trileptal 300 mg tablet salut selaput
Novartis Farma S.p.A., Torre Annunziata, Italia untuk Novartis Pharma AG, Basel, Swiss

Trileptal suspensi oral
Delpharm Huningue SAS, Huningue, Perancis untuk Novartis Pharma AG, Basel, Swiss

Jika Anda memiliki pertanyaan mengenai obat ini, mohon hubungi dokter atau apoteker Anda.

PIL berdasarkan BPL v3.2 25-Nov-2024