Generic Name: Gabapentin
Trade Name: Neurontin
CCDS Effective Date: July 19, 2024
Supersedes: January 20, 2023

TRADE NAME(S) OF THE MEDICINAL PRODUCT

NEURONTIN

QUALITATIVE AND QUANTITATIVE COMPOSITION (Active Ingredients)

Gabapentin is supplied in capsules containing 300 mg of active drug substance for oral administration.

Gabapentin is a white to off-white crystalline solid. It is freely soluble in water and both basic and acidic aqueous solutions.

List of Excipients

Each capsule also contains lactose, cornstarch, and talc.

PHARMACEUTICAL FORM

Capsules

CLINICAL PARTICULARS

Therapeutic Indications

Epilepsy
Gabapentin is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 3 years and older. Safety and effectiveness for adjunctive therapy in pediatric patients younger than 3 years have not been established (see Section **Posology and Method of Administration**: *Pediatric Patients Aged 3 to 12 Years*).

Neuropathic Pain
Gabapentin is indicated for the treatment of neuropathic pain in adults aged 18 years and older. Safety and effectiveness in patients younger than 18 years have not been established.

Posology and Method of Administration

General
Gabapentin is given orally with or without food.

When in the judgment of the clinician there is a need for dose reduction, discontinuation, or substitution with an alternative medication, this should be done gradually over a minimum of 1 week.

Epilepsy

Adults and Pediatric Patients Older Than 12 Years of Age

In clinical trials, the effective dosing range was 900 mg/day to 1800 mg/day. Therapy may be initiated by administering 300 mg three times a day on Day 1, or by titrating the dose (TABLE 1). Thereafter, the dose can be increased in three equally divided doses up to a maximum dose of 2400 mg/day. The maximum time between doses in the three times a day schedule should not exceed 12 hours to prevent breakthrough convulsions.

TABLE 1
DOSING CHART – INITIAL TITRATION

Dose	Day 1	Day 2	Day 3
900 mg	300 mg QD[a]	300 mg BID[b]	300 mg TID[c]

[a] QD = Once a day (in the evening).
[b] BID = Two times a day (in the morning and evening).
[c] TID = Three times a day (in the morning, at noon and in the evening).

Pediatric Patients Aged 3-12 Years

The starting dose should range from 10 to 15 mg/kg/day given in equally divided doses (three times a day), and the effective dose reached by upward titration over a period of approximately 3 days. The effective dose of gabapentin in pediatric patients aged 5 years and older is 25 to 35 mg/kg/day given in equally divided doses (three times a day). The effective dose in pediatric patients aged 3 to less than 5 years is 40 mg/kg/day given in equally divided doses (three times a day). Doses up to 50 mg/kg/day have been well tolerated in a long-term clinical study. The maximum time interval between doses should not exceed 12 hours.

It is not necessary to monitor gabapentin plasma concentrations to optimize gabapentin therapy. Further, gabapentin may be used in combination with other antiepileptic drugs without concern for alteration of the plasma concentrations of gabapentin or serum concentrations of other antiepileptic drugs.

Neuropathic Pain in Adults

Neurontin should be titrated to a maximum dose of 1800 mg/day. Titration to an effective dose can be progress rapidly and can be accomplished over a few days by administering 300 mg once a day on Day 1, 300 mg twice a day on Day 2 and 300 mg three times a day on Day 3, (TABLE 1).

Thereafter, the dose can be increased using increments of 300 mg/day given in three divided doses to a maximum of 1800 mg/day.

Dose Adjustment in Impaired Renal function in Patients with Neuropathic Pain or Epilepsy

Dose adjustment is recommended in patients with compromised renal function (TABLE 2) and/or in those undergoing hemodialysis.

TABLE 2 MAINTENANCE DOSE OF NEURONTIN IN ADULTS WITH REDUCED RENAL FUNCTION			
Renal Function Creatinine Clearance (mL/minute)	Total Daily Dose[a] (mg/day) NORMAL DOSE		
≥80	900	1200	2400
50-79	600	600	1200
30-49	300	300	600
15-29	150[b]	300	300
<15	150[b]	150[b]	150[b]

[a] Total daily dose should be administered as three times a day regimen. Doses used to treat patients with normal renal function (creatinine clearance ≥80 mL/min) range from 900 mg/day to 2400 mg/day. Reduced doses are for patients with renal impairment (creatinine clearance <79 mL/min).

[b] To be administered as 300 mg every other day.

Dose Adjustment in Patients Undergoing Hemodialysis

For patients undergoing hemodialysis who have never received gabapentin, a loading dose of 300 mg to 400 mg is recommended, and then 200 mg to 300 mg of gabapentin following each 4 hours of hemodialysis.

On dialysis-free days there should be no treatment with Neurontin.

If Neurontin discontinued and/or an alternate anticonvulsant medication is added to the therapy, this should be done gradually over a minimum of 1 week.

Method and Duration of Administration

Neurontin capsules should be swallowed whole with sufficient fluid intake. Administration may be made during or between meals. In three-times daily administration, care should be taken that the interval between two single doses does not exceed 12 hours.

Whether a missed dose of Neurontin (this means more than 12 hours passed since the last administration) should be made up for by taking an additional dose of Neurontin later or not is at the physician's discretion.

In concurrent treatment with magnesium or aluminum containing antacids, Neurontin should be taken at least 2 hours after administration of the antacid. This largely avoids a reduction in gabapentin bioavailability.

The duration of administration depends on the clinical requirements. In the treatment of epilepsy, usually, long-term therapy is required.

If therapy with Neurontin capsules should be discontinued, the dose reduced, or switched to another drug, this should be done gradually over a minimum of one week, although there is no evidence of a rebound phenomenon (increased occurrence of epileptic seizures following abrupt

withdrawal of therapy).

In the treatment of neuropathic pain, efficacy and safety has not been examined in clinical studies for treatment periods longer than 5 months.

Contraindications

Gabapentin is contraindicated in patients who are hypersensitive to gabapentin or the product's components.

Neurontin is contraindicated in patients with acute pancreatitis.

Neurontin is not effective against primarily generalized seizures, such as absences.

Neurontin capsules are not to be administered to patients with galactosemia (galactose intolerance) due to their lactose content.

Notes
No systematic studies in patients 65 years or older have been conducted with Neurontin. However, clinical investigations in this age group do not indicate an adverse event profile different from that observed in younger patients.

Epilepsy
There is not yet sufficient experience for add-on therapy in children below 3 years of age.

Special Warnings and Precautions for Use

General
Although there is no evidence of rebound seizures with gabapentin, abrupt withdrawal of anticonvulsants in epileptic patients may precipitate status epilepticus (see Section **Posology and Method of Administration** – General).

Gabapentin is generally not considered effective in the treatment of absence seizures.

Gabapentin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall). There have also been post-marketing reports of confusion, loss of consciousness and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medication.

Concomitant Use with Opioids and Other CNS Depressants
Patients who require concomitant treatment with opioids may experience increases in gabapentin concentrations. Patients who require concomitant treatment with CNS (central nervous system) depressants, including opioids should be carefully observed for signs of CNS depression, such as somnolence, sedation and respiratory depression and the dose of gabapentin or concomitant

treatment with CNS depressants including opioids should be reduced appropriately (see Section **Interactions with Other Drugs and Other Forms of Interaction**).

Caution is advised when prescribing gabapentin concomitantly with opioids due to risk of CNS depression. In a population-based, observational, nested case-control study of opioid users, co-prescription of opioids and gabapentin was associated with an increased risk for opioid-related death compared to opioid prescription use alone (adjusted odds ratio [aOR], 1.49 [95% CI, 1.18 to 1.88, p<0.001]).

Drug Rash with Eosinophilia and Systemic Symptoms
Severe, life-threatening, systemic hypersensitivity reactions such as drug rash with eosinophilia and systemic symptoms (DRESS) have been reported in patients taking antiepileptic drugs including gabapentin.

It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. Gabapentin should be discontinued if an alternative etiology for the signs or symptoms cannot be established.

Anaphylaxis
Gabapentin can cause anaphylaxis. Signs and symptoms in reported cases have included difficulty breathing, swelling of the lips, throat, and tongue, and hypotension requiring emergency treatment. Patients should be instructed to discontinue gabapentin and seek immediate medical care should they experience signs or symptoms of anaphylaxis.

Abuse and Dependence
Cases of abuse and dependence have been reported in the post-marketing database. As with any CNS active drug, carefully evaluate patients for a history of drug abuse and/or psychiatric disorders.

Caution should be applied when considering gabapentin use in patients with current substance abuse or a history of substance abuse, who may be at higher risk for gabapentin abuse.

Patients treated with gabapentin should be monitored for signs and symptoms of gabapentin abuse or dependence, such as the development of tolerance, dose escalation and drug-seeking behavior.

Withdrawal symptoms
After discontinuation of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed in some patients. Withdrawal symptoms may occur shortly after the discontinuation, usually within 48 hours. Most frequently reported symptoms include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise.

Women of childbearing potential/Contraception
Gabapentin use in the first trimester of pregnancy may cause major birth defects in the unborn

child. Gabapentin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the fetus. Women of childbearing potential must use effective contraception during treatment (see Section **Fertility, Pregnancy and Lactation**).

Information for patients
To assure safe and effective use of gabapentin, the following information and instructions should be given to patients:

1. You should inform your physician about any prescription or non-prescription medications, alcohol, or drugs you are now taking or are planning to take during your treatment with gabapentin.

2. You should inform your physician if you are pregnant, or if you are planning to become pregnant, or if you become pregnant while you are taking gabapentin.

3. Gabapentin is excreted in human milk, and the effect on the nursing infant is unknown. You should inform your physician if you are breast feeding an infant (see Section **Fertility, Pregnancy and Lactation**: Lactation).

4. Gabapentin may impair your ability to drive a car or operate potentially dangerous machinery. Until it is known that this medication does not affect your ability to engage in these activities, do not drive a car or operate potentially dangerous machinery.

5. You should not allow more than 12 hours between gabapentin doses to prevent breakthrough convulsions.

6. Prior to initiation of treatment with gabapentin, the patient should be instructed that a rash or other signs or symptoms of hypersensitivity such as fever or lymphadenopathy may herald a serious medical event and that the patient should report any such occurrence to a physician immediately.

Interactions with Other Drugs and Other Forms of Interaction

There are spontaneous and literature case reports of respiratory depression, sedation, and death associated with gabapentin when co-administered with CNS depressants, including opioids. In some of these reports, the authors considered the combination of gabapentin with opioids to be a particular concern in frail patients, in the elderly, in patients with serious underlying respiratory disease, with polypharmacy, and in those patients with substance abuse disorders.

Morphine: In a study involving healthy volunteers (N=12), when a 60-mg controlled-release morphine capsule was administered 2 hours prior to a 600-mg gabapentin capsule, mean gabapentin AUC increased by 44% compared to gabapentin administered without morphine. This was associated with an increased pain threshold (cold pressor test). The clinical significance of such changes has not been defined. Morphine pharmacokinetic parameter values were not affected by administration of gabapentin 2 hours after morphine. The observed opioid-mediated side effects associated with morphine plus gabapentin did not differ significantly from morphine plus placebo.

The magnitude of interaction at other doses is not known (see Section **Special Warnings and Precautions for Use**).

No interaction between gabapentin and phenobarbital, phenytoin, valproic acid, or carbamazepine has been observed. Gabapentin steady-state pharmacokinetics are similar for healthy subjects and patients with epilepsy receiving these antiepileptic agents.

Co-administration of gabapentin with oral contraceptives containing norethindrone and/or ethinyl estradiol, does not influence the steady-state pharmacokinetics of either component.

Co-administration of gabapentin with antacids containing aluminum and magnesium, reduces gabapentin bioavailability by about 20%. It is recommended that gabapentin be taken about 2 hours following antacid administration.

Renal excretion of gabapentin is unaltered by probenecid.

A slight decrease in renal excretion of gabapentin that is observed when it is co-administered with cimetidine is not expected to be of clinical importance.

Alcohol or centrally acting drugs of abuse may exaggerate some gabapentin central nervous system side effects (e.g., somnolence and ataxia).

Laboratory tests
False positive readings were reported with the Ames N-Multistix SG® dipstick test when gabapentin was added to other anticonvulsant drugs. To determine urinary protein, the more specific sulfosalicylic acid precipitation procedure is recommended.

Fertility, Pregnancy and Lactation

Fertility
There is no effect on fertility in animal studies (see Section **Preclinical Safety Data**: *Impairment of fertility*).

Pregnancy
Gabapentin crosses the human placenta.

The risk of birth defects is increased by a factor of 2 – 3 in the offspring of mothers treated with an antiepileptic medicinal product.

Data from an observational study, which included more than 1700 pregnancies exposed to gabapentin based on routinely collected data from administrative and medical registers in Denmark, Finland, Norway, and Sweden, do not suggest substantially increased risks of major congenital malformations, adverse birth outcomes, or abnormal postnatal neurodevelopmental outcomes in gabapentin-exposed pregnancies.

For major congenital malformations, the adjusted prevalence ratios (aPRs) and 95% confidence intervals (CI) in the standard meta-analysis for first trimester gabapentin exposed vs. unexposed to antiepileptic drugs was 0.99 (0.80-1.23).

Overall, there were no statistically significant findings for stillbirth, small for gestational age, low Apgar score, and microcephaly. The aPRs were 1.21 (1.02-1.44) for low birth weight, 1.16 (1.00-1.35) for preterm birth.

In pediatric population exposed in utero, the study did not provide evidence of an increased risk for neurodevelopmental outcomes, such as attention deficit hyperactivity disorder (ADHD), autism spectrum disorders (ASD), and intellectual disabilities.

Neonatal withdrawal syndrome has been reported in newborns exposed in utero to gabapentin. Co-exposure to gabapentin and opioids during pregnancy may increase the risk of neonatal withdrawal syndrome.

Studies in animals have shown reproductive toxicity (see Section **Preclinical Safety Data**: *Teratogenesis*). Gabapentin should not be used during pregnancy unless the potential benefit to the mother clearly outweighs the potential risk to the fetus.

Lactation

Gabapentin is excreted in human milk. Because the effect on the nursing infant is unknown, caution should be exercised when gabapentin is administered to a nursing mother. Gabapentin should be used in nursing mothers only if the benefits clearly outweigh the risks.

Effects on Ability to Drive and Use Machines

Patients should be advised not to drive a car or operate potentially dangerous machinery until it is known that this medication does not affect their ability to engage in these activities.

Undesirable Effects

Epilepsy

Gabapentin has been evaluated for safety in more than 2000 subjects and patients in adjunctive therapy studies and was well tolerated. Of these, 543 patients participated in controlled clinical trials. Since gabapentin was most often administered in combination with other antiepileptic agents, it was not possible to determine which agent(s), if any, was associated with adverse events.

Incidence in Controlled Adjunctive Therapy Clinical Trials

TABLE 3 lists the treatment-emergent signs and symptoms that occurred in at least 1% of patients with partial seizures participating in placebo-controlled adjunctive therapy studies. In these studies, either gabapentin or placebo was added to the patient's current antiepileptic drug therapy. Adverse events were usually reported as mild to moderate.

TABLE 3

Summary of Treatment-emergent Signs and Symptoms in ≥1% of Gabapentin-treated Patients in Placebo-controlled Adjunctive Therapy Studies

COSTART Body System/Adverse Event	Gabapentin[a] N=543		Placebo[a] N=378	
	n of Pts	(%)	n of Pts	(%)
Body as a Whole				
Abdominal pain	10	1.8	9	2.4
Back pain	10	1.8	2	0.5
Fatigue	60	11.0	19	5.0
Fever	7	1.3	5	1.3
Headache	44	8.1	34	9.0
Viral infection	7	1.3	8	2.1
Cardiovascular				
Vasodilation	6	1.1	1	0.3
Digestive System				
Constipation	8	1.5	3	0.8
Dental abnormalities	8	1.5	1	0.3
Diarrhea	7	1.3	8	2.1
Dyspepsia	12	2.2	2	0.5
Increased appetite	6	1.1	3	0.8
Mouth or throat dry	9	1.7	2	0.5
Nausea and/or Vomiting	33	6.1	27	7.1
Hematologic and Lymphatic				
Leukopenia	6	1.1	2	0.5
WBC decreased	6	1.1	2	0.5
Metabolic and Nutritional				
Peripheral edema	9	1.7	2	0.5
Weight increase	16	2.9	6	1.6
Musculoskeletal System				
Fracture	6	1.1	3	0.8
Myalgia	11	2.0	7	1.9
Nervous System				
Amnesia	12	2.2	0	0.0
Ataxia	68	12.5	21	5.6
Confusion	9	1.7	7	1.9

TABLE 3

Summary of Treatment-emergent Signs and Symptoms in ≥1% of Gabapentin-treated Patients in Placebo-controlled Adjunctive Therapy Studies

COSTART Body System/Adverse Event	Gabapentin[a] N=543		Placebo[a] N=378	
	n of Pts	(%)	n of Pts	(%)
Coordination abnormal	6	1.1	1	0.3
Depression	10	1.8	4	1.1
Dizziness	93	17.1	26	6.9
Dysarthria	13	2.4	2	0.5
Emotional lability	6	1.1	5	1.3
Insomnia	6	1.1	7	1.9
Nervousness	13	2.4	7	1.9
Nystagmus	45	8.3	15	4.0
Somnolence	105	19.3	33	8.7
Thinking abnormal	9	1.7	5	1.3
Tremor	37	6.8	12	3.2
Twitching	7	1.3	2	0.5
Respiratory System				
Coughing	10	1.8	5	1.3
Pharyngitis	15	2.8	6	1.6
Rhinitis	22	4.1	14	3.7
Skin and Appendages				
Abrasion	7	1.3	0	0.0
Acne	6	1.1	5	1.3
Pruritus	7	1.3	2	0.5
Rash	8	1.5	6	1.6
Special Senses				
Amblyopia	23	4.2	4	1.1
Diplopia	32	5.9	7	1.9
Urogenital System				
Impotence	8	1.5	4	1.1

[a] Includes concomitant antiepileptic drug therapy
Pts - patients

Other Adverse Events Observed During All Clinical Trials

Adjunctive Therapy

Those events that occurred in at least 1% of the study participants with epilepsy who received gabapentin as adjunctive therapy in any clinical study and that are not described in the previous section as frequently occurring treatment-emergent signs and symptoms during placebo-controlled studies are summarized below.

Body as a Whole: asthenia, malaise, facial edema
Cardiovascular System: hypertension
Digestive System: flatulence, anorexia, gingivitis
Hematologic and Lymphatic Systems: purpura, most often described as bruises resulting from physical trauma
Musculoskeletal System: arthralgia
Nervous System: vertigo, hyperkinesia, increased, decreased or absent reflexes, paresthesia, anxiety, hostility
Respiratory System: pneumonia
Urogenital System: urinary tract infection
Special Senses: abnormal vision, most often described as a visual disturbance

Geriatric Use
Fifty-nine individuals aged 65 years or older received gabapentin in pre-marketing clinical trials. Side effects reported among these patients did not differ in kind from those reported in younger individuals. For patients with compromised renal function, the dose should be adjusted (see Section **Posology and Method of Administration**).

Pediatric Use
The most commonly observed adverse events reported with the use of gabapentin in combination with other antiepileptic drugs in children aged 3 to 12 years , not seen in equal frequency among placebo-treated patients, were viral infection, fever, nausea and/or vomiting, and somnolence.

TABLE 4

Incidence of Treatment-emergent Adverse Events Children Aged 3 to 12 Years in Controlled Add-on Trials (Events in at least 2% of Gabapentin patients and numerically more frequent than in the placebo group)

Body System/Adverse Event	Gabapentin[a] N=119 %	Placebo[a] N=128 %
Body as a Whole		
Viral infection	10.9	3.1
Fever	10.1	3.1
Weight increase	3.4	0.8
Fatigue	3.4	1.6
Digestive System		
Nausea and/or vomiting	8.4	7.0
Nervous System		
Somnolence	8.4	4.7
Hostility	7.6	2.3

TABLE 4		
Incidence of Treatment-emergent Adverse Events Children Aged 3 to 12 Years in Controlled Add-on Trials (Events in at least 2% of Gabapentin patients and numerically more frequent than in the placebo group)		
Body System/Adverse Event	**Gabapentin[a] N=119 %**	**Placebo[a] N=128 %**
Emotional lability	4.2	1.6
Dizziness	2.5	1.6
Hyperkinesia	2.5	0.8
Respiratory System		
Bronchitis	3.4	0.8
Respiratory infection	2.5	0.8
[a] Includes concomitant antiepileptic drug therapy		

Other events in more than 2% of children that occurred equally or more frequent in the placebo group included: pharyngitis, upper respiratory infection, headache, rhinitis, convulsions, diarrhea, anorexia, coughing, and otitis media.

Withdrawal from Treatment Due to Adverse Events

Adjunctive Therapy

Approximately 7% of the more than 2000 healthy volunteers and patients with epilepsy, spasticity, or migraine who received gabapentin in clinical studies withdrew due to adverse events.

In all clinical studies, the most frequently occurring events that contributed to discontinuation of gabapentin included somnolence, ataxia, dizziness, fatigue, and nausea and/or vomiting. Almost all participants had multiple complaints, none of which could be characterized as primary.

Pediatric

Approximately 8% of the 292 children aged 3 to 12 years who received gabapentin in clinical trials discontinued treatment because of an adverse event. The adverse events most commonly associated with withdrawal in children were somnolence, hyperkinesia, and hostility.

Neuropathic Pain:

TABLE 5				
Summary of Treatment-emergent Signs and Symptoms in ≥1% of Gabapentin-treated Patients in Neuropathic Pain Placebo-controlled Studies				
COSTART Body System/Adverse Event	**Gabapentin N=821**		**Placebo N=537**	
	n of Pts	**(%)**	**n of Pts**	**(%)**
Body as a Whole				

TABLE 5

Summary of Treatment-emergent Signs and Symptoms in ≥1% of Gabapentin-treated Patients in Neuropathic Pain Placebo-controlled Studies

COSTART Body System/Adverse Event	Gabapentin N=821		Placebo N=537	
	n of Pts	(%)	n of Pts	(%)
Abdominal pain	23	2.8	17	3.2
Accidental injury	32	3.9	17	3.2
Asthenia	41	5.0	25	4.7
Back pain	19	2.3	8	1.5
Flu syndrome	21	2.6	14	2.6
Headache	45	5.5	33	6.1
Infection	38	4.6	40	7.4
Pain	30	3.7	36	6.7
Digestive System				
Constipation	19	2.3	9	1.7
Diarrhea	46	5.6	24	4.5
Dry mouth	27	3.3	5	0.9
Dyspepsia	16	1.9	10	1.9
Flatulence	14	1.7	6	1.1
Nausea	45	5.5	29	5.4
Vomiting	16	1.9	13	2.4
Metabolic and Nutritional				
Peripheral edema	44	5.4	14	2.6
Weight gain	14	1.7	0	0.0
Nervous System				
Abnormal gait	9	1.1	0	0.0
Amnesia	15	1.8	3	0.6
Ataxia	19	2.3	0	0.0
Confusion	15	1.8	5	0.9
Dizziness	173	21.1	35	6.5
Hypesthesia	11	1.3	3	0.6
Somnolence	132	16.1	27	5.0
Thinking abnormal	12	1.5	0	0.0
Tremor	9	1.1	6	1.1
Vertigo	8	1.0	2	0.4
Respiratory System				
Dyspnea	9	1.1	3	0.6
Pharyngitis	15	1.8	7	1.3

TABLE 5				
Summary of Treatment-emergent Signs and Symptoms in ≥1% of Gabapentin-treated Patients in Neuropathic Pain Placebo-controlled Studies				
COSTART Body System/Adverse Event	**Gabapentin N=821**		**Placebo N=537**	
	n of Pts	**(%)**	**n of Pts**	**(%)**
Skin and Appendages				
Rash	14	1.7	4	0.7
Special Senses				
Amblyopia	15	1.8	2	0.4

Post-marketing Experience

Sudden, unexplained deaths have been reported where a causal relationship to treatment with gabapentin has not been established.

Additional post-marketing adverse events reported include blood creatine phosphokinase increased, rhabdomyolysis, acute kidney failure, agitation, allergic reaction including urticaria, alopecia, anaphylaxis, angioedema, blood glucose fluctuations in patients with diabetes, breast hypertrophy, chest pain, drug rash with eosinophilia and systemic symptoms, elevated liver function tests (LFTs), erythema multiforme, fall, generalized edema, gynecomastia, hallucinations, hepatitis, hypersensitivity including systemic reactions, hyponatremia, jaundice, loss of consciousness, movement disorders such as choreoathetosis, dyskinesia, and dystonia, myoclonus, palpitation, pancreatitis, sexual dysfunction (including changes in libido, ejaculation disorders and anorgasmia), Stevens-Johnson syndrome, thrombocytopenia, tinnitus, and urinary incontinence.

After discontinuation of short-term and long-term treatment with gabapentin, withdrawal symptoms have been observed in some patients. Most frequently reported symptoms include anxiety, insomnia, nausea, pains, sweating, tremor, headache, depression, feeling abnormal, dizziness, and malaise (see Section **Special Warnings and Precautions for Use**).

Overdose

Acute, life-threatening toxicity has not been observed with gabapentin overdoses of up to 49 g. Symptoms of the overdoses included dizziness, double vision, slurred speech, drowsiness, loss of consciousness, lethargy and mild diarrhea. All patients recovered fully with supportive care. Reduced absorption of gabapentin at higher doses may limit drug absorption at the time of overdosing and, hence, minimize toxicity from overdoses.

Although gabapentin can be removed by hemodialysis, based on prior experience it is usually not required. However, in patients with severe renal impairment, hemodialysis may be indicated.

An oral lethal dose of gabapentin was not identified in mice and rats given doses as high as 8000 mg/kg. Signs of acute toxicity in animals included ataxia, labored breathing, ptosis,

hypoactivity, or excitation.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Other analgesics and antipyretics, ATC code: N02BF01.

Gabapentin readily enters the brain and prevents seizures in a number of animal models of epilepsy. Gabapentin does not possess affinity for either GABAA or GABAB receptor nor does it alter the metabolism of GABA. It does not bind to other neurotransmitter receptors of the brain and does not interact with sodium channels. Gabapentin binds with high affinity to the α2δ (alpha-2-delta) subunit of voltage-gated calcium channels and it is proposed that binding to the α2δ subunit may be involved in gabapentin's anti-seizure effects in animals. Broad panel screening does not suggest any other drug target other than α2δ.

Evidence from several pre-clinical models inform that the pharmacological activity of gabapentin may be mediated via binding to α2δ through a reduction in release of excitatory neurotransmitters in regions of the central nervous system. Such activity may underlie gabapentin's anti-seizure activity. The relevance of these actions of gabapentin to the anticonvulsant effects in humans remains to be established.

Gabapentin also displays efficacy in several pre-clinical animal pain models. Specific binding of gabapentin to the α2δ subunit is proposed to result in several different actions that may be responsible for analgesic activity in animal models. The analgesic activities of gabapentin may occur in the spinal cord as well as at higher brain centers through interactions with descending pain inhibitory pathways. The relevance of these pre-clinical properties to clinical action in humans is unknown.

Pharmacokinetic Properties

Gabapentin bioavailability is not dose proportional. That is, as the dose is increased, bioavailability decreases. Following oral administration, peak plasma gabapentin concentrations are observed within 2 to 3 hours. Absolute bioavailability of gabapentin capsules is approximately 60%. Food, including a high-fat diet, has no effect on gabapentin pharmacokinetics.

Gabapentin elimination from plasma is best described by linear pharmacokinetics.

The elimination half-life of gabapentin is independent of dose and averages 5 to 7 hours.

Gabapentin pharmacokinetics are not affected by repeated administration, and steady-state plasma concentrations are predictable from single dose data. Although plasma gabapentin concentrations were generally between 2 μg/mL and 20 μg/mL in clinical studies, such concentrations were not predictive of safety or efficacy. Plasma gabapentin concentrations are dose proportional at doses of 300 mg or 400 mg given every 8 hours. Pharmacokinetic parameters are given in TABLE 6.

TABLE 6
Summary of Gabapentin Mean (%RSD) Steady-state Pharmacokinetic Parameters Following Q8H Administration

Pharmacokinetic Parameter	300 mg (n = 7)		400 mg (n = 11)	
C_{max} (µg/mL)	4.02	(24)	5.50	(21)
t_{max} (h)	2.7	(18)	2.1	(47)
$t_{1/2}$ (h)	5.2	(12)	6.1	ND
$AUC_{0-\infty}$/(µg•h/mL)	24.8	(24)	33.3	(20)
Ae%	NA	NA	63.6	(14)

ND = Not determined
NA = Not available

Gabapentin is not bound to plasma proteins and has a volume of distribution equal to 57.7 L. In patients with epilepsy, gabapentin concentrations in the Cerebrospinal fluid (CSF) are approximately 20% of corresponding steady-state trough plasma concentrations. Gabapentin is eliminated solely by renal excretion. There is no evidence of metabolism in man. Gabapentin does not induce hepatic mixed function oxidase enzymes responsible for drug metabolism.

In elderly patients, and in patients with impaired renal function, gabapentin plasma clearance is reduced. Gabapentin elimination-rate constant, plasma clearance, and renal clearance are directly proportional to creatinine clearance.

Gabapentin is removed from plasma by hemodialysis. Dose adjustment in patients with compromised renal function or in those undergoing hemodialysis is recommended (see Section **Posology and Method of Administration**, **Dose Adjustment in Impaired Renal function in Patients with Neuropathic Pain or Epilepsy** and **Dose Adjustment in Patients Undergoing Hemodialysis**).

Gabapentin pharmacokinetics in children were determined in 24 healthy subjects between the ages of 4 and 12 years. In general, gabapentin plasma concentrations in children are similar to those in adults.

Preclinical Safety Data

Carcinogenesis
Gabapentin was given in the diet to mice at 200, 600, and 2000 mg/kg/day and to rats at 250, 1000, and 2000 mg/kg/day for 2 years. A statistically significant increase in the incidence of pancreatic acinar cell tumors was found only in male rats at the highest dose. Peak plasma drug concentrations in rats at 2000 mg/kg/day were 10 times higher than plasma concentrations in humans given at 3600 mg/day. The pancreatic acinar cell tumors in male rats were low-grade malignancies, which did not affect survival, did not metastasize or invade surrounding tissue, and were similar to those seen in concurrent controls. The relevance of these pancreatic acinar cell tumors in male rats to carcinogenic risk in humans is unclear.

Mutagenesis
Gabapentin demonstrated no genotoxic potential. It was not mutagenic *in vitro* in standard assays using bacterial or mammalian cells. Gabapentin did not induce structural chromosome aberrations in mammalian cells *in vitro* or *in vivo*, and did not induce micronucleus formation in the bone marrow of hamsters.

Impairment of Fertility
No adverse effects on fertility or reproduction were observed in rats at doses up to 2000 mg/kg (approximately 5 times the maximum daily human dose on a mg/m^2 basis).

Teratogenesis
Gabapentin did not increase the incidence of malformations, compared to controls, in the offsprings of mice, rats, or rabbits at doses up to 50, 30 and 25 times respectively, the daily human dose of 3600 mg (4, 5 or 8 times, respectively, the human daily dose on a mg/m^2 basis).

Gabapentin induced delayed ossification in the skull, vertebrae, forelimbs, and hind limbs in rodents, indicative of fetal growth retardation. These effects occurred when pregnant mice received oral doses of 1000 or 3000 mg/kg/day during organogenesis and in rats given 2000 mg/kg/day prior to and during mating and throughout gestation. These doses are approximately 1 to 5 times the human dose of 3600 mg on a mg/m^2 basis.

No effects were observed in pregnant mice given 500 mg/kg/day (approximately half of the daily human dose on a mg/m^2 basis).

An increased incidence of hydroureter and/or hydronephrosis was observed in rats given 2000 mg/kg/day in a fertility and general reproduction study, 1500 mg/kg/day in a teratology study, and 500, 1000, and 2000 mg/kg/day in a perinatal and postnatal study. The significance of these findings is unknown, but they have been associated with delayed development. These doses are also approximately 1 to 5 times the human dose of 3600 mg on a mg/m^2 basis.

In a teratology study in rabbits, an increased incidence of post-implantation fetal loss, occurred in female rabbits given 60, 300, and 1500 mg/kg/day during organogenesis. These doses are approximately 1/4 to 8 times the daily human dose of 3600 mg on a mg/m^2 basis.

Neurontin Capsule 300 mg:

Store below 30°C.

ON DOCTOR'S PRESCRIPTION ONLY

HARUS DENGAN RESEP DOKTER

SUPPLY

Neurontin Capsules are available in the form:

Capsule 300 mg, box of 10 blisters @ 10 capsules, Reg. No. DKIxxxxxxxxxxx

Neurontin Capsule 300 mg

Manufactured by:
Viatris Pharmaceuticals LLC, Vega Baja, Puerto Rico

Packed and released by:
Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

Imported by:
PT Fonko International Pharmaceuticals, Bekasi, Indonesia

Marketed by:
PT Aurogen Pharma Indonesia, Jakarta, Indonesia

Nama Generik: Gabapentin
Nama Dagang: Neurontin®
Tanggal Berlaku CCDS: 24 Mei 2023
Menggantikan: 20 Januari 2023
Disetujui oleh BPOM:

Leaflet kemasan: Informasi bagi pengguna

Neurontin® 300 mg Kapsul

Gabapentin

Baca semua bagian leaflet ini dengan cermat sebelum mulai menggunakan obat ini karena berisi informasi penting bagi Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, hubungi dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekalipun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Isi leaflet ini:

1. Nama obat
Neurontin®

2. Bentuk sediaan
Kapsul.

3. Deskripsi obat
Neurontin® disediakan dalam bentuk kapsul yang berisi 300 mg senyawa obat aktif untuk pemberian oral.

4. Apa kandungan obat ini?
Neurontin® merupakan padatan kristalin berwarna putih hingga putih tulang. Obat ini mudah larut dalam air serta dalam larutan basa dan asam dengan pelarut air.

Daftar Eksipien

Setiap kapsul juga mengandung laktosa, pati jagung, dan talk.

5. Kekuatan obat
300 mg

6. Apa kegunaan obat ini?
Epilepsi
Neurontin® diindikasikan sebagai terapi tambahan dalam pengobatan kejang sebagian dengan dan tanpa penyebaran sekunder ke kedua sisi otak pada orang dewasa dan anak-anak berusia 3 tahun ke atas. Keamanan dan efektivitas terapi tambahan pada pasien anak berusia kurang dari 3 tahun masih belum ditetapkan.

Nyeri Neuropatik
Neurontin® diindikasikan untuk pengobatan nyeri neuropatik/nyeri akibat kerusakan saraf pada orang dewasa berusia 18 tahun ke atas. Keamanan dan efektivitas pada pasien yang berusia kurang dari 18 tahun masih belum ditetapkan.

7. Berapa banyak dan seberapa sering Anda harus menggunakan obat ini? Apa yang harus dilakukan jika ada dosis terlewat?
Selalu gunakan obat ini dengan tepat sesuai anjuran dokter atau apoteker Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin. Jangan mengonsumsi obat ini melebihi dosis yang telah ditentukan.

Dokter akan menentukan dosis yang tepat bagi Anda.

Untuk epilepsi, dosis yang direkomendasikan adalah

Orang dewasa dan remaja (*Di Atas 12 Tahun*)
Minumlah obat dalam jumlah sesuai petunjuk dokter. Dokter biasanya akan menaikkan dosis Anda secara bertahap. Kisaran dosis yang efektif adalah 900 mg/hari hingga 1800 mg/hari. Dosis awal dapat diberikan sebesar 300 mg tiga kali sehari pada Hari ke-1 atau dengan menaikkan dosis secara bertahap. Selanjutnya, dosis dapat ditingkatkan sesuai petunjuk dokter Anda hingga maksimal 2400 mg setiap hari. Dokter Anda akan memberi tahu Anda untuk meminum obat dalam 3 dosis terpisah, yaitu satu kali di pagi hari, satu kali di siang hari, dan satu kali di malam hari.

Anak-anak berusia 3–12 tahun
Dosis yang diberikan kepada anak Anda akan ditentukan oleh dokter karena akan dihitung sesuai berat badan anak Anda. Dosis awal berkisar antara 10 hingga 15 mg/kg/hari yang diberikan dalam dosis yang terbagi sama rata (tiga kali sehari) dan dosis efektifnya akan ditingkatkan secara bertahap dalam jangka waktu sekitar 3 hari. Dosis efektif untuk mengendalikan epilepsi adalah 25–35 mg/kg/hari (tiga kali sehari) pada anak-anak berusia 5 tahun atau lebih, dan 40 mg/kg/hari (tiga kali sehari) pada anak-anak berusia 3 tahun hingga kurang dari 5 tahun. Obat biasanya diberikan dalam 3 dosis terpisah, dengan meminum kapsul setiap hari, biasanya satu kali di pagi hari, satu kali di siang hari, dan satu kali di malam hari.

Dalam kasus nyeri neuropatik, dosis yang dianjurkan adalah

Orang Dewasa
Minumlah kapsul dalam jumlah yang diresepkan oleh dokter Anda. Dokter biasanya akan menaikkan dosis Anda secara bertahap. Peningkatan dosis secara bertahap hingga dosis yang efektif dapat berlangsung cepat dan dapat dicapai dalam waktu beberapa hari dengan memberikan 300 mg satu kali

sehari pada Hari ke-1, 300 mg dua kali sehari pada Hari ke-2, dan 300 mg tiga kali sehari pada Hari ke-3. Selanjutnya, dosis dapat ditingkatkan sesuai petunjuk dokter Anda dengan menggunakan peningkatan 300 mg/hari hingga maksimal 1800 mg/hari. Dokter Anda akan memberi tahu Anda untuk meminum obat dalam 3 dosis terpisah, yaitu satu kali di pagi hari, satu kali di siang hari, dan satu kali di malam hari.

Jika Anda meminum Neurontin® tiga kali sehari, jangan biarkan ada jeda lebih dari 12 jam antara setiap dosis.

Jika Anda memiliki masalah pada ginjal atau Anda sedang menjalani cuci darah
Dokter mungkin akan meresepkan jadwal pemberian dosis dan/atau dosis yang berbeda jika Anda menderita gangguan ginjal atau sedang menjalani cuci darah. Untuk pasien yang menjalani cuci darah, disarankan untuk menggunakan dosis awal 300 mg hingga 400 mg dan kemudian 200 mg hingga 300 mg gabapentin setiap kali selesai menjalani 4 jam prosedur cuci darah. Pada hari-hari tanpa cuci darah, maka pasien tidak boleh menggunakan Neurontin.

Jika Anda adalah pasien lansia (berusia di atas 65 tahun), Anda dapat meminum dosis normal Neurontin® kecuali jika Anda menderita gangguan ginjal. Dokter mungkin akan meresepkan jadwal pemberian dosis dan/atau dosis yang berbeda jika Anda menderita gangguan ginjal.

Jika Anda merasa bahwa efek Neurontin® terlalu kuat atau terlalu lemah, maka konsultasikan kepada dokter atau apoteker Anda sesegera mungkin.

Metode pemberian

Neurontin® adalah untuk penggunaan oral. Telan selalu kapsul dengan air minum yang banyak. Neurontin® dapat diminum sesudah atau sebelum makan.

Jika Anda melewatkan dosis, segera beri tahu dokter atau perawat Anda.

Jika Anda lupa meminum Neurontin®
Jika Anda melewatkan dosis, minum segera setelah Anda ingat, kecuali jika sudah memasuki waktu untuk dosis berikutnya. Jangan meminum dosis ganda untuk menggantikan dosis yang terlewat.

Jika Anda berhenti meminum Neurontin®
Jangan berhenti meminum Neurontin® kecuali dokter menginstruksikan demikian. Jika pengobatan Anda dihentikan, maka harus diturunkan secara bertahap minimal satu minggu. Apabila Anda berhenti meminum Neurontin® tiba-tiba atau sebelum dokter menginstruksi demikian, ada kemungkinan peningkatan risiko kejang pada pasien epilepsi.

Setelah menghentikan pengobatan dengan Neurontin® untuk jangka panjang maupun jangka pendek, perlu diketahui bahwa Anda mungkin akan mengalami efek samping tertentu, yaitu sindrom putus obat. Efek sampingnya dapat meliputi kejang-kejang, kegelisahan, sulit tidur, mual, nyeri, berkeringat, gemetar, sakit kepala, depresi, merasa tidak enak badan, pusing, dan merasa kurang sehat. Efek samping ini biasanya muncul dalam kurun 48 jam setelah berhenti mengonsumsi Neurontin®. Jika Anda mengalami sindrom putus obat, hubungi dokter.

8. Kapan seharusnya Anda tidak menggunakan obat ini?

Jangan menggunakan Neurontin® jika:

- Anda alergi terhadap gabapentin atau bahan-bahan lainnya dalam obat ini
- jika Anda mengalami tanda-tanda seperti sakit perut berkepanjangan, merasa mual dan muntah, harap hubungi dokter Anda segera karena bisa jadi ini merupakan gejala-gejala pankreatitis akut (peradangan pankreas)

- jika Anda telah diberi tahu oleh dokter bahwa Anda memiliki intoleransi terhadap beberapa jenis galaktosa, hubungi dokter Anda sebelum menggunakan obat ini.

Jangan menggunakan Neurontin® jika ada di antara kondisi di atas yang berlaku untuk Anda. Jika kurang yakin, konsultasikan dengan dokter atau perawat Anda sebelum menggunakan Neurontin®.

Neurontin® tidak efektif untuk mengobati kejang dengan penyebaran primer ke kedua sisi otak, seperti kejang dengan gejala pandangan kosong.

Neurontin® tidak dianjurkan untuk digunakan pada anak-anak berusia di bawah 3 tahun.

9. Apa yang perlu dipertimbangkan sebelum menggunakan obat ini?

Konsultasikan dengan dokter atau perawat Anda sebelum menggunakan Neurontin® jika:
– jika Anda menderita gangguan ginjal maka dokter akan meresepkan jadwal pemberian dosis yang berbeda
– jika Anda sedang menjalani cuci darah (untuk menghilangkan produk buangan karena gagal ginjal), beri tahu dokter Anda jika Anda mengalami nyeri otot dan/atau rasa lemah.
– jika pernah menyalahgunakan atau kecanduan alkohol, obat keras, atau obat-obatan terlarang, Anda lebih berisiko mengalami ketergantungan Neurontin®

Ketergantungan

Sejumlah orang mungkin akan mengalami ketergantungan Neurontin® (harus selalu mengonsumsi obat ini). Jika berhenti mengonsumsinya, mereka akan mengalami sindrom putus obat (baca bagian **Jika Anda berhenti meminum Neurontin®**). Apabila Anda khawatir mengalami ketergantungan obat ini, harap konsultasikan kepada dokter.

Gejala berikut ini dapat menjadi pertanda bahwa Anda mengalami ketergantungan Neurontin®.
– merasa perlu mengonsumsi obat ini dalam periode lebih lama dari yang ditentukan dokter
– merasa perlu mengonsumsi obat ini melebihi dosis yang telah ditentukan
– mengonsumsi obat ini untuk kebutuhan selain yang telah ditentukan
– berulang kali gagal dalam mencoba menghentikan atau mengendalikan konsumsi obat ini
– merasa tidak enak badan ketika berhenti mengonsumsi obat ini, tetapi kembali sehat saat mengonsumsinya lagi

Jika Anda merasakan salah satu gejala di atas, hubungi dokter untuk menentukan penanganan terbaik bagi Anda, termasuk waktu yang tepat dan cara yang aman untuk berhenti mengonsumsinya.

Informasi penting tentang potensi reaksi serius

Sejumlah kecil orang yang meminum Neurontin® mengalami reaksi alergi atau reaksi kulit yang berpotensi serius, yang dapat berkembang menjadi gangguan yang lebih serius jika tidak ditangani. Anda perlu mengetahui gejala-gejala apa saja yang perlu diperhatikan saat Anda menggunakan Neurontin®.

10. Apa obat-obatan lain atau makanan yang harus dihindari saat menggunakan obat ini?

Beri tahu dokter atau apoteker jika Anda menggunakan, baru saja menggunakan, atau mungkin saja telah menggunakan obat-obatan lain atau alkohol yang sedang Anda gunakan atau rencananya akan Anda gunakan. Secara khusus, beri tahu dokter (atau apoteker) Anda jika Anda sedang menggunakan atau baru-baru ini menggunakan obat apa pun untuk mengatasi kejang, gangguan tidur, depresi, kecemasan, atau gangguan saraf atau kejiwaan lainnya.

Obat-obatan yang mengandung opioid seperti morfin

Jika Anda sedang menggunakan obat-obatan yang mengandung opioid (seperti morfin), harap beri tahu dokter atau apoteker Anda karena opioid dapat meningkatkan efek Neurontin®. Selain itu,

kombinasi Neurontin® dengan opioid dapat menimbulkan gejala-gejala seperti rasa mengantuk, sedasi, dan/atau penurunan napas, atau kematian.

Antasid untuk gangguan pencernaan
Jika Neurontin® dan antasid yang mengandung aluminium dan magnesium diberikan secara bersamaan, maka penyerapan Neurontin® dari lambung bisa jadi mengalami penurunan. Oleh karena itu dianjurkan agar Neurontin® diminum paling cepat dua jam setelah meminum antasid.

Neurontin®
– diperkirakan tidak akan berinteraksi dengan obat-obatan antiepilepsi lainnya atau pil kontrasepsi.
– dapat mengganggu beberapa hasil uji laboratorium, jika Anda harus menjalani tes urine, harap beri tahu dokter atau rumah sakit perihal apa saja yang Anda minum.

Neurontin® dengan makanan
Neurontin® dapat diminum dengan atau tanpa makanan.

11. Apakah obat ini aman untuk perempuan hamil dan menyusui?
Jika Anda hamil atau menyusui, menduga Anda mungkin sedang hamil, atau sedang merencanakan kehamilan, mintalah saran dari dokter atau apoteker Anda sebelum mengonsumsi obat ini.

Kehamilan
Neurontin® tidak boleh diminum selama kehamilan, kecuali jika dokter menyatakan sebaliknya.
Wanita usia subur harus menggunakan metode kontrasepsi yang efektif.
Jika dikonsumsi selama kehamilan, gabapentin dapat menyebabkan sindrom putus obat pada bayi baru lahir. Risiko ini dapat meningkat jika gabapentin dikonsumsi bersamaan dengan analgesik opioid (obat untuk menangani nyeri parah).

Hubungi dokter Anda segera jika Anda hamil, merasa diri Anda hamil, atau merencanakan kehamilan saat menggunakan Neurontin®.

Menyusui
Gabapentin, bahan aktif dalam Neurontin® akan disalurkan melalui ASI. Karena efeknya terhadap bayi masih belum diketahui, maka tidak disarankan untuk menyusui selama menggunakan Neurontin®.

12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin saat menggunakan obat ini?
Neurontin® dapat memicu pusing, kantuk, dan kelelahan. Anda dilarang mengemudi, mengoperasikan mesin yang rumit, atau mengambil bagian dalam aktivitas berbahaya lainnya hingga Anda mengetahui apakah obat ini memengaruhi kemampuan Anda untuk menjalankan aktivitas tersebut.

13. Apa potensi efek yang tidak diinginkan saat menggunakan obat ini?
Beri tahu dokter atau apoteker Anda sesegera mungkin jika Anda merasa sakit selama menggunakan Neurontin®.

Semua obat dapat menimbulkan efek samping. Kadang-kadang efek sampingnya bersifat serius, tetapi sebagian besar tidak. Anda mungkin perlu mendapatkan penanganan medis jika mengalami beberapa efek samping tertentu. Mungkin akan sulit untuk memastikan apakah efek samping yang dialami disebabkan oleh penggunaan Neurontin®; akibat kondisi tubuh Anda; atau efek samping dari obat-obatan lain yang mungkin Anda gunakan, karena alasan ini penting kiranya bagi Anda untuk memberi tahu dokter perihal perubahan kondisi Anda.

Jika Anda mengalami efek samping apa pun, jangan menghentikan penggunaan Neurontin® tanpa berkonsultasi dahulu dengan dokter atau apoteker Anda.

Beri tahu dokter atau perawat jika Anda mengalami efek berikut ini dan itu membuat Anda khawatir:
- pusing* atau kepala terasa ringan
- merasa lelah atau mengantuk*
- perilaku tidak bersahabat*
- aktif berlebihan yang tidak wajar*
- mudah lupa, hilang konsentrasi, atau kebingungan
- sulit berbicara
- perubahan berat badan Anda*
- konstipasi, diare
- mual dan/atau muntah*, gangguan pencernaan
- mulut kering, gusi bengkak memerah
- nyeri atau kram otot, nyeri punggung
- pembengkakan tangan atau kaki
- pilek atau hidung tersumbat
- demam*
- bronkitis (radang saluran napas)*, infeksi paru*
- radang tenggorokan dan rasa tidak nyaman saat menelan, batuk.

Daftar di atas termasuk efek samping Neurontin® yang lebih umum. Efek samping tersebut biasanya ringan dan berlangsung singkat.

Beri tahu dokter Anda sesegera mungkin, jika Anda mengalami kondisi berikut ini:
- rasa lemah, tidak stabil saat berjalan termasuk jatuh, penurunan koordinasi, atau reaksi melambat
- perubahan suasana hati yang tidak lazim* atau perilaku seperti gelisah, tegang, atau perasaan yang terlalu meluap
- tanda-tanda muncul serangan baru atau peningkatan iritabilitas atau agitasi (lekas marah atau gelisah)
- tanda-tanda depresi
- melihat atau mendengar sesuatu yang sebenarnya tidak ada, pemikiran yang tidak rasional
- pandangan kabur atau pandangan ganda, gerakan sentakan mata yang tidak terkendali, kesulitan melihat
- tanda-tanda infeksi yang sering seperti demam, menggigil berat, radang tenggorokan, atau tukak di mulut.
- kesulitan bernapas atau napas dangkal (depresi pernapasan)
- hilangnya kesadaran

Efek samping dalam daftar di atas yang bertanda * telah dilaporkan secara spesifik pada anak-anak yang menggunakan Neurontin®.

Beri tahu dokter Anda segera atau datangi Unit Gawat Darurat di rumah sakit terdekat jika Anda mengalami yang berikut ini:
- tanda-tanda alergi yang tiba-tiba seperti ruam, gatal atau kaligata, demam, pembengkakan kelenjar getah bening, pembengkakan wajah, bibir, lidah, atau bagian tubuh lainnya, sesak napas, mengi, atau kesulitan bernapas.

Daftar di atas termasuk efek samping yang sangat serius. Anda mungkin memerlukan penanganan medis segera atau rawat inap.

Beri tahu dokter atau apoteker jika Anda merasakan kondisi apa pun lainnya yang membuat Anda merasa tidak nyaman.

Efek samping lain yang tidak tercantum di atas mungkin juga dialami oleh beberapa orang.

Sebagian dari efek samping ini (misalnya, perubahan fungsi tiroid, struktur tulang, kolesterol tinggi, kadar gula dalam darah, atau tekanan darah Anda) hanya dapat diketahui oleh dokter jika dilakukan tes darah dari waktu ke waktu untuk melihat kemajuan Anda.

Melaporkan efek samping
Jika Anda mengalami efek samping, konsultasikan dengan dokter atau apoteker Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda dapat membantu memberikan lebih banyak informasi perihal keamanan obat ini.

14. Tanda-tanda dan gejala-gejala overdosis
Dosis melebihi anjuran dapat menyebabkan peningkatan efek samping antara lain: pusing, penglihatan ganda, bicara cadel, rasa mengantuk, hilangnya kesadaran, lesu, dan diare ringan.

15. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
Hubungi dokter Anda atau datangi segera unit gawat darurat (UGD) rumah sakit terdekat jika Anda mengonsumsi Neurontin® lebih dari yang diresepkan dokter Anda. Bawa semua kapsul yang belum Anda minum, bersama dengan wadah dan labelnya sehingga rumah sakit dapat dengan mudah mengetahui obat apa yang telah Anda minum.

16. Bagaimana cara menyimpan obat ini?
Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Simpan pada suhu di bawah 30 °C.

Simpan dalam kemasan aslinya untuk melindunginya dari cahaya.

Jangan membuang obat melalui saluran pembuangan air atau bersama sampah rumah tangga. Tanyakan kepada apoteker Anda cara membuang obat yang sudah tidak lagi digunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

17. Berapa lama umur simpan obat setelah kemasannya dibuka untuk pertama kali?
Jangan gunakan obat ini setelah melewati tanggal kedaluwarsa yang tercantum pada label karton. Tanggal kedaluwarsa mengacu pada hari terakhir dari bulan yang tertera.

18. Nomor hak pemasaran
Kapsul 300 mg, dus 10 blister @ 10 kapsul, No. Reg. DKIxxxxxxxxxxx

19. Nama dan alamat pemohon dan/atau pemilik obat sesuai dengan ketentuan yang berlaku
Diproduksi oleh:
Viatris Pharmaceuticals LLC, Vega Baja, Puerto Rico

Dikemas dan dirilis oleh:
Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

Diimpor oleh:
PT Fonko International Pharmaceuticals, Bekasi, Indonesia

Dipasarkan oleh:
PT Aurogen, Pharma Indonesia, Jakarta, Indonesia

20. Tanggal Revisi PIL
12/2024

21. Peringatan khusus

HARUS DENGAN RESEP DOKTER

Tanggal Berlaku CCDS: 24 Mei 2023
Menggantikan: 20 Januari 2023
Disetujui oleh BPOM: XX XXX XXXX