Generic Name: Pregabalin
Trade Name: **LYRICA™**
CCDS Effective Date: May 23, 2023
Supersedes: February 15, 2022

NAME OF THE MEDICINAL PRODUCT

LYRICA™ 50 mg hard capsules.
LYRICA™ 75 mg hard capsules.
LYRICA™ 150 mg hard capsules.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 50 mg, 75 mg, or 150 mg of pregabalin.

List of Excipients
Each capsule also contains lactose, corn starch, and talc.

PHARMACEUTICAL FORM

Hard capsule
50 mg capsule: White hard gelatine capsule, marked “Pfizer” on the cap and “PGN 50” on the body with black ink. The body is also marked with a black band.

75 mg capsule: White and orange hard gelatine capsule, marked “Pfizer” on the cap and “PGN 75” on the body with black ink.

150 mg capsule: White hard gelatine capsule, marked “Pfizer” on the cap and “PGN 150” on the body with black ink.

CLINICAL PARTICULARS

Therapeutic indications

Neuropathic Pain

LYRICA™ (pregabalin) is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

LYRICA™ is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.

Generalised Anxiety Disorder

LYRICA™ is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Fibromyalgia

LYRICA™ is indicated to reduce pain in the management of fibromyalgia.

Posology and method of administration

The dose range is 150 to 600 mg per day given in either two or three divided doses.

LYRICA™ (pregabalin) is given with or without food.

Neuropathic Pain

The recommended starting dose for LYRICA™ (pregabalin) is 75 mg BID (150 mg/day), with or without food. In clinical trials, the efficacy of pregabalin was demonstrated in patients dosed in a range of 150 to 600 mg/day. For the majority of patients, 150 mg BID will be the optimal dose. Efficacy of pregabalin has been demonstrated within the first week. However, based on individual patient response and tolerability, the dose may be increased to 150 mg BID after an interval of 3 to 7 days, and if needed, to a maximum dose of 300 mg BID after an additional week.

Epilepsy

The recommended effective starting dose for LYRICA™ (pregabalin) is 75 mg BID (150 mg/day), with or without food. In clinical trials, the efficacy of pregabalin was demonstrated in patients dosed in a range of 150 to 600 mg/day. Efficacy of pregabalin has been demonstrated as early as 1 week. However, based on individual patient response and tolerability, the dose may be increased to 150 mg BID after 1 week, and if needed, to a maximum dose of 300 mg BID after an additional week.

Generalised Anxiety Disorder

The dose range is 150 to 600 mg per day given as two or three divided doses. The need for treatment should be reassessed regularly.

Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dosage may be increased to 300 mg per day after 1 week. Following an additional week the dosage may be increased to 450 mg per day. The maximum dosage of 600 mg per day may be achieved after an additional week.

Fibromyalgia

The recommended dose of pregabalin is 300 to 450 mg/day given in two divided doses. Dosing should begin at 75 mg two times a day (150 mg/day) and may be increased to 150 mg two times a day (300 mg/day) within 1 week based on efficacy and tolerability. Patients who do not experience sufficient benefit with 300 mg/day may be further increased to 225 mg two times a day (450 mg/day). Although LYRICA™ was also studied at 600 mg/day, there is no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose dependent adverse reactions, treatment with dose above 450 mg/day is not recommended. Because LYRICA™ is eliminated primarily by renal excretion, adjust the dose in patients with reduced renal function.

Discontinuation of Pregabalin

In accordance with current clinical practice, if LYRICA™ (pregabalin) has to be discontinued either in neuropathic pain or epilepsy, it is recommended this should be done gradually over a minimum of 1 week.

Patients with Renal Impairment

Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. As pregabalin clearance is directly proportional to creatinine clearance (see section **Pharmacokinetic properties**, Pharmacokinetics in special patient groups), dosage reduction in patients with compromised renal function must be individualized according to creatinine clearance (CL_{cr}), as indicated in Table 1 determined using the following formula:

$$CL_{cr}(mL/min) = \frac{[140 - age\ (years)] \times weight\ (kg)}{72 \times serum\ creatinine\ (mg/dL)} \quad (\times\ 0.85\ for\ female\ patients)$$

For patients receiving haemodialysis, the pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose should be given immediately following every 4-hour haemodialysis treatment (see Table 1).

Table 1: Pregabalin dosage adjustment based on renal function

Creatinine Clearance (CL_{cr}) (mL/min)	Total Pregabalin Daily Dose*		Dose Regimen
	Starting Dose (mg/day)	Maximum Dose (mg/day)	
≥60	150	600	BID
≥30 – <60	75	300	QD or BID
≥15 – <30	25 – 50	150	QD or BID
<15	25	75	QD
Supplementary dosage following haemodialysis (mg)			
	25	100	Single dose+

BID = Two divided doses.
QD = Single daily dose.
*Total daily dose (mg/day) should be divided as indicated by dose regimen to provide mg/dose.
+Supplementary dose is a single additional dose.

Use in Patients with Hepatic Impairment

No dosage adjustment is required for patients with hepatic impairment (see section **Pharmacokinetic properties**, Pharmacokinetics in special patient groups).

Use in Children and Adolescents (12 to 17 years of age)

The safety and effectiveness of pregabalin in pediatric patients below the age of 12 years and adolescents has not been established.

The use in children is not recommended (see section **Preclinical safety data**).

Use in the Elderly (over 65 years of age)

Elderly patients may require a dose reduction of pregabalin due to decreased renal function (see section **Pharmacokinetic properties**, Pharmacokinetics in special patients groups, Elderly (over 65 years of age)).

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Special warnings and special precautions for use

Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption should not take this medicine.

In accordance with current clinical practice, some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycemic medications.

There have been reports in the post-marketing experience of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur.

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

In the post-marketing experience, transient visual blurring and other changes in visual acuity have been reported in patients treated with pregabalin. Discontinuation of pregabalin may result in resolution or improvement of these visual symptoms.

There are insufficient data for the withdrawal of concomitant antiepileptic medicinal products, once seizure control with pregabalin in the add-on situation has been reached, in order to reach monotherapy on pregabalin.

After discontinuation of short-term and long-term treatment with pregabalin, withdrawal symptoms have been observed in some patients. The following events have been mentioned: insomnia, headache, nausea, anxiety, diarrhea, hyperhidrosis, flu syndrome, nervousness, depression, pain, sweating and dizziness. The patients should be informed about this at the start of treatment.

Pregabalin is not known to be active at receptor sites associated with drugs of abuse. Cases of misuse, abuse and dependence have been reported in the post-marketing database. As with any CNS active drug, carefully evaluate patients for history of drug abuse and/or psychiatric disorders. Caution should be applied when considering pregabalin use in patients with current substance abuse or a history of substance abuse, who are at higher risk for pregabalin abuse.

Patients treated with pregabalin should be observed for signs and symptoms of pregabalin misuse, abuse or dependence (e.g., development of tolerance, dose escalation, drug-seeking behavior).

Although the effects of discontinuation on the reversibility of renal failure have not been systematically studied, improved renal function following discontinuation or dose reduction of pregabalin has been reported.

Concerning discontinuation of long-term treatment of pregabalin there are no data of the incidence and severity of withdrawal symptoms in relation to duration of use and dosage of pregabalin.

Although there has been no causal relationship identified between exposure to pregabalin and congestive heart failure, there have been post-marketing reports of congestive heart failure in some patients receiving pregabalin. In short-term trials of

patients without clinically significant heart or peripheral vascular disease, there was no apparent association between peripheral edema and cardiovascular complications such as hypertension or congestive heart failure. Because there are limited data on congestive heart failure patients, pregabalin should be used with caution in these patients (see section **Undesirable effects**).

Caution is advised when prescribing pregabalin concomitantly with opioids due to risk of CNS depression. In an observational study of opioid users, those patients who took pregabalin concomitantly with an opioid had an increased risk for opioid-related death compared to opioid use alone (adjusted odds ratio [aOR], 1.68 [95% CI, 1.19 to 2.36]).

In the treatment of central neuropathic pain due to spinal cord injury the incidence of adverse events in general, CNS adverse events and especially somnolence was increased. This may be attributed to an additive effect due to concomitant medication (e.g., anti-spasticity agents) needed for this condition. This should be considered when prescribing pregabalin in this condition.

Women of childbearing potential/Contraception

Pregabalin use in the first trimester of pregnancy may cause major birth defects in the unborn child. Pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus. Women of childbearing potential must use effective contraception during treatment (see section **Pregnancy and lactation**).

Interaction with other medicinal products and other forms of interaction

Since LYRICA™ (pregabalin) is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (<2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism *in vitro*, and is not bound to plasma proteins, it is unlikely to produce, or be subject to, pharmacokinetic interactions.

Accordingly, in *in vivo* studies no clinically relevant pharmacokinetic interactions were observed between pregabalin and phenytoin, carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. Population pharmacokinetic analysis indicated that oral antidiabetics, diuretics, insulin, phenobarbital, tiagabine and topiramate had no clinically significant effect on pregabalin clearance.

Co-administration of pregabalin with the oral contraceptives norethisterone and/or ethinyl estradiol does not influence the steady-state pharmacokinetics of either agent. Pregabalin may potentiate the effects of ethanol and lorazepam. In controlled clinical trials, multiple oral doses of pregabalin co-administered with oxycodone, lorazepam, or ethanol did not result in clinically important effects on respiration. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone.

In the post-marketing experience, there are reports of respiratory failure, coma and deaths in patients taking pregabalin and other CNS depressant medications, including in patients who are substance abusers. There are post-marketing reports of events related to reduced lower gastrointestinal tract function (e.g., intestinal obstruction, paralytic ileus, constipation) when pregabalin was co-administered with medications that have the potential to produce constipation, such as opioid analgesics.

No specific pharmacodynamic interaction studies were conducted in elderly volunteers. Interaction studies have only been performed in adults.

Pregnancy and lactation

Pregnancy

There is a limited amount of data on the use of LYRICA™ (pregabalin) in pregnant women.

Data from an observational study, which included more than 2,700 pregnancies exposed to pregabalin based on routinely collected data from administrative and medical registers in Denmark, Finland, Norway, and Sweden, is as follow:

Major congenital malformations

The adjusted prevalence ratios (aPRs) and 95% confidence intervals (CI) in the standard meta-analysis for first-trimester pregabalin monotherapy-exposed vs. unexposed to anti-epileptic drugs was 1.14 (0.96-1.35).

The analyses on specific malformations showed higher risks for malformations of the nervous system, the eye, orofacial clefts, urinary malformations and genital malformations, but numbers were small and estimates imprecise.

Birth and postnatal neurodevelopmental outcomes

There were no statistically significant findings for stillbirth, low birth weight, preterm birth, small for gestational age, low Apgar score, and microcephaly.

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

Studies in animals have shown reproductive toxicity (see section **Preclinical safety data**). LYRICA™ should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus. Effective contraception must be used in women of childbearing potential (see section **Special warnings and special precautions for use**).

Lactation

Pregabalin is excreted in the milk of lactating women (see section **Pharmacokinetic properties**). As the safety of pregabalin in infants is not known, breast-feeding is not recommended during treatment with pregabalin. A decision must be made whether to discontinue breast-feeding or to discontinue from pregabalin therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Effects on ability to drive and use machines

LYRICA™ may have minor or moderate influence on the ability to drive and use machines. LYRICA™ may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medication affects their ability to perform these activities.

Undesirable effects

The LYRICA™ (pregabalin) clinical programme involved over 12,000 patients who were exposed to pregabalin, of whom over 7000 were in double-blind placebo controlled trials. The most commonly reported adverse reactions were dizziness and somnolence. Adverse reactions were usually mild to moderate in intensity. In all controlled studies, the discontinuation rate due to adverse reactions was 14% for patients receiving pregabalin and 5% for patients receiving placebo. The most common adverse reactions resulting in discontinuation from pregabalin treatment groups were dizziness and somnolence.

In the table below all adverse drug reactions, which occurred at an incidence greater than placebo and in more than one patient are listed by class. The frequency of these terms has been based on all-causality adverse drug reactions in the clinical trial data set (very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100) and rare (<1/1000).

The adverse reactions listed may also be associated with the underlying disease and/or concomitant medications.

In the treatment of central neuropathic pain due to spinal cord injury the incidence of adverse events in general, CNS adverse events and especially somnolence was increased (see section **Special warnings and special precautions for use**).

System Organ Class	**Adverse Drug Reactions**
Infection and infestations	
Common	Nasopharyngitis
Blood and lymphatic system disorders	
Uncommon	Neutropenia
Metabolism and nutrition disorders	

System Organ Class	Adverse Drug Reactions
Common	Appetite increased
Uncommon	Anorexia, hypoglycemia
Psychiatric disorders	
Common	Euphoric mood, confusion, irritability, depression, disorientation, insomnia, libido decreased
Uncommon	Hallucination, restlessness, agitation, depressed mood, elevated mood, mood swings, depersonalization, abnormal dreams, word finding difficulty, libido increased, anorgasmia
Rare	Panic attack, disinhibition, apathy
Nervous system disorders	
Very Common	Dizziness, somnolence
Common	Ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoesthesia, sedation, balance disorder, lethargy
Uncommon	Syncope, myoclonus, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, speech disorder, hyporeflexia, hyperaesthesia, burning sensation
Rare	Stupor, parosmia, hypokinesia, ageusia, dysgraphia
Eye disorders	
Common	Vision blurred, diplopia
Uncommon	Peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, eye pain, asthenopia, photopsia, dry eye, lacrimation increased, eye irritation
Rare	Oscillopsia, altered visual depth perception, mydriasis, strabismus, visual brightness
Ear and labyrinth disorders	
Common	Vertigo
Uncommon	Hyperacusis
Cardiac disorders	
Uncommon	Tachycardia, atrioventricular block first degree, sinus bradycardia
Rare	Sinus tachycardia, sinus arrhythmia
Vascular disorders	
Uncommon	Hypotension, hypertension, hot flushes, flushing, peripheral coldness
Respiratory, thoracic and mediastinal disorders	
Uncommon	Dyspnoea, epistaxis, cough, nasal congestion, rhinitis, snoring
Rare	Throat tightness, nasal dryness
Gastrointestinal disorders	
Common	Vomiting, constipation, flatulence, abdominal distension, dry mouth

System Organ Class	Adverse Drug Reactions
Uncommon	Gastrooesophageal reflux disease, salivary hypersecretion, hypoesthesia oral
Rare	Ascites, pancreatitis, dysphagia
Skin and subcutaneous tissue disorders	
Uncommon	Rash papular, urticaria, sweating
Rare	Cold sweat
Musculoskeletal and connective tissue disorders	
Common	Muscle cramp, arthralgia, back pain, pain in limb, cervical spasm
Uncommon	Joint swelling, myalgia, muscle twitching, neck pain, muscle stiffness
Rare	Rhabdomyolysis
Renal and urinary disorders	
Uncommon	Urinary incontinence, dysuria
Rare	Renal failure, oliguria
Reproductive system and breast disorders	
Uncommon	Erectile dysfunction, sexual dysfunction, ejaculation delayed, dysmenorrhoea
Rare	Breast pain, amenorrhea, breast discharge, breast enlargement
General disorders and administration site conditions	
Common	Oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue
Uncommon	Generalised oedema, chest tightness, pain pyrexia, thirst, chills, asthenia
Investigations	
Common	Weight increased
Uncommon	Blood creatine phosphokinase increased, alanine aminotransferase increased, aspartate aminotransferase increased, blood glucose increased, platelet count decreased, blood potassium decreased, weight decreased
Rare	White blood cell count decreased, blood creatinine increased

After discontinuation of short-term and long term treatment with pregabalin withdrawal symptoms have been observed in some patients. The following events have been mentioned: allergic reaction, hypersensitivity, pruritus, insomnia, headache, nausea, diarrhoea, flu syndrome, congestive heart failure, nervousness, depression, pain, sweating and dizziness. The patient should be informed about this at the start of the treatment.

Concerning discontinuation of long-term treatment of pregabalin there are no data of the incidence and severity of withdrawal symptoms in relation to duration of use and dosage of pregabalin.

The following adverse drug reactions were reported during POST-MARKETING SURVEILLANCE:

Immune system disorder: Uncommon: Hypersensitivity; Rare: Angioedema, allergic reaction.

Nervous system disorders: Very Common: Headache; Uncommon: Loss of consciousness, mental impairment.

Eye disorders: Rare: Keratitis.§

Cardiac disorders: Rare: Congestive heart failure.

Respiratory, thoracic and mediastinal disorders: Rare: Pulmonary oedema.§

Gastrointestinal disorders: Common: Nausea, diarrhoea; Rare: Swollen tongue.

Skin and subcutaneous tissue disorders: Uncommon: Face swelling, pruritus; Rare: Stevens-Johnson syndrome.

Renal and urinary disorders: Rare: Urinary retention.

Reproductive system and breast disorders: Rare: Gynecomastia.§

General disorders and administration site conditions: Uncommon: Malaise.

§Adverse drug reaction frequency estimated using "The Rule of 3".

Reporting of adverse reactions
Reporting suspected adverse events after authorization 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 reaction via Pharmacovigilance Center/National MESO at e-meso.pom.go.id, and/or to pv@dexagroup.com and pharmacovigilance.id@aurobindo.com.

Overdose

In overdoses up to 15 g, no unexpected adverse reactions were reported. Treatment of LYRICA™ (pregabalin) overdose should include general supportive measures and may include haemodialysis if necessary (see section **Posology and method of administration** with renal impairment).

In the post-marketing experience, the most commonly reported adverse events observed when pregabalin was taken in overdose included affective disorder, somnolence, confusional state, depression, agitation, and restlessness. Seizures were also reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics, ATC code: N02BF02.

The active substance, pregabalin, is a gamma-aminobutyric acid analogue ((S)-3-(aminomethyl)-5-methylhexanoic acid).

Mechanism of action

Pregabalin binds to an auxiliary subunit (α_2-δ protein) of voltage-gated calcium channels in the central nervous system.

Evidence from animal models with nerve damage has shown that pregabalin reduces calcium dependent release of pronociceptive neurotransmitters in the spinal cord possibly by disrupting calcium trafficking and/or reducing calcium currents. Evidence from other animal models of nerve damage suggest the antinociceptive activities of pregabalin may also be mediated through interactions with the descending noradrenergic and serotonergic pathways.

Clinical experience

Neuropathic pain
Efficacy has been shown in studies in diabetic neuropathy and post-herpetic neuralgia. Efficacy has not been studied in other models of neuropathic pain.

Pregabalin has been studied in 9 controlled clinical studies of up to 13 weeks with twice a day dosing (BID) and up to 8 weeks with three times a day (TID) dosing. Overall, the safety and efficacy profiles for BID and TID dosing regimens were similar.

In clinical trials up to 13 weeks for both peripheral and central neuropathic pain, a reduction in pain was seen by Week 1 and was maintained throughout the treatment period.

In controlled clinical trials in peripheral neuropathic pain 35% of the pregabalin treated patients and 18% of the patients on placebo had a 50% improvement in pain score. For patients not experiencing somnolence, such an improvement was observed in 33% of patients treated with pregabalin and 18% of patients on placebo. For patients who experienced somnolence the responder rates were 48% on pregabalin and 16% on placebo.

In the controlled clinical trial in central neuropathic pain 22% of the pregabalin treated patients and 7% of the patients on placebo had a 50% improvement in pain score.

Fibromyalgia

The efficacy of LYRICA™ for management of fibromyalgia was established in one 14-week, double-blind, placebo-controlled, multicenter study (F1) and one 6-month, randomized withdrawal study (F2). Studies F1 and F2 enrolled patients with a diagnosis of fibromyalgia using the American College of Rheumatology (ACR) criteria (history of widespread pain for 3 months, and pain present at 11 or more of the 18 specific tender point sites). The studies showed a reduction in pain by visual analog scale. In addition, improvement was demonstrated based on a patient global assessment (PGIC), and on the Fibromyalgia Impact Questionnaire (FIQ).

Study F1: This 14-week study compared LYRICA™ total daily doses of 300 mg, 450 mg and 600 mg with placebo. Patients were enrolled with a minimum mean baseline pain score of greater than or equal to 4 on an 11-point numeric pain rating scale and a score of greater than or equal to 40 mm on the 100 mm pain visual analog scale (VAS). The baseline mean pain score in this trial was 6.7. Responders to placebo in an initial one-week run-in phase were not randomized into subsequent phases of the study. A total of 64% of patients randomized to LYRICA™ completed the study. There was no evidence of a greater effect on pain scores of the 600 mg daily dose than the 450 mg daily dose, but there was evidence of dose-dependent adverse reactions. Some patients experienced a decrease in pain as early as Week 1, which persisted throughout the study. The results are summarized in Figure 1 and Table 2.

For various degrees of improvement in pain from baseline to study endpoint, Figure 1 shows the fraction of patients achieving that degree of improvement. The figure is cumulative. Patients who did not complete the study were assigned 0% improvement. Some patients experienced a decrease in pain as early as Week 1, which persisted throughout the study.

Figure 1: Patients Achieving Various Levels of Pain Relief – Fibromyalgia Study F1

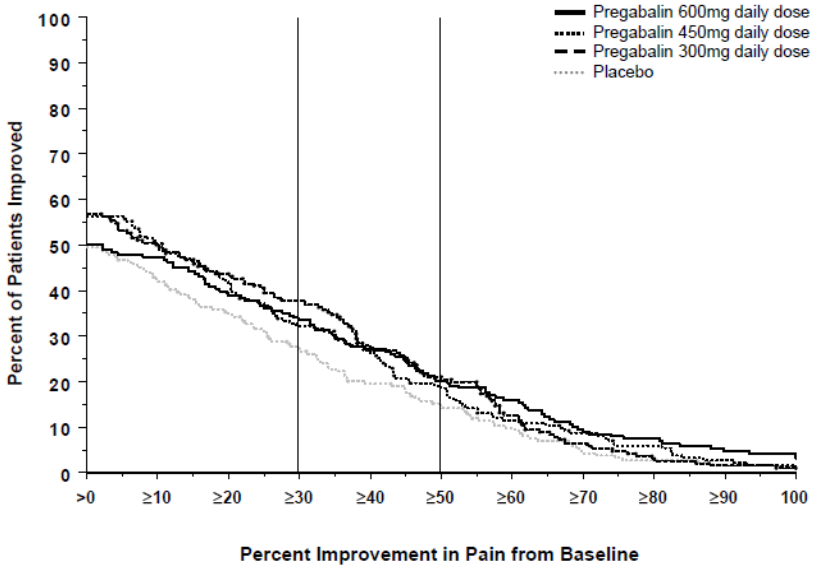


Table 2: Patient Global Response in Fibromyalgia Study F1

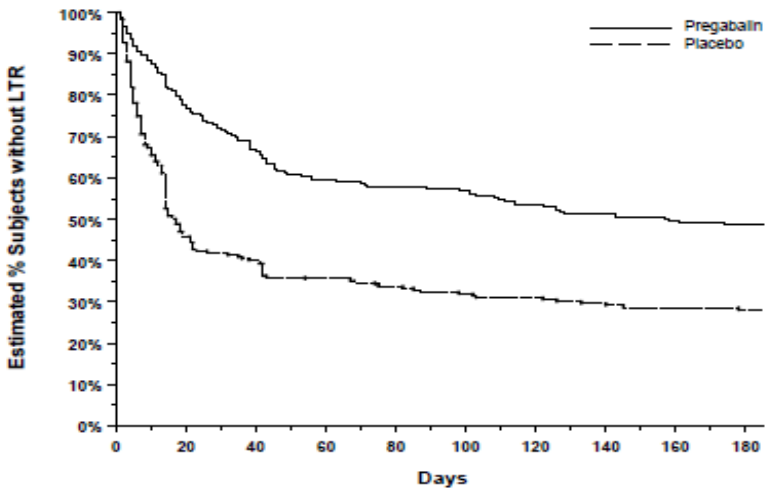
Patient Global Impression of Change		
Treatment Group (mg/day)		
Placebo	47.6	(40.0, 55.2)
PGB 300	68.1	(60.9, 75.3)
PGB 450	77.8	(71.5, 84.0)
PGB 600	66.1	(59.1, 73.1)
PGB = Pregabalin.		

Study F2: This randomized withdrawal study compared LYRICA™ with placebo. Patients were titrated during a 6-week open-label dose optimization phase to a total daily dose of 300 mg, 450 mg, or 600 mg. Patients were considered to be responders if they had both: 1) at least a 50% reduction in pain (VAS) and, 2) rated their overall improvement on the PGIC as "much improved" or "very much improved". Those who responded to treatment were then randomized in the double-blind treatment phase to either the dose achieved in the open-label phase or to placebo. Patients were treated for up to 6 months following randomization. Efficacy was assessed by time to loss of therapeutic response, defined as 1) less than 30% reduction in pain (VAS) from open-label baseline during two consecutive visits of the double-blind phase, or 2) worsening of FM symptoms necessitating an alternative treatment. Fifty-four percent of patients were able to titrate to an effective and tolerable dose of LYRICA™ during the 6-week open-label phase. Of the patients entering the randomized treatment phase assigned to remain on LYRICA™, 38% of patients completed 26 weeks of treatment versus 19% of placebo-treated patients.

When considering return of pain or withdrawal due to adverse events as loss of response (LTR), treatment with LYRICA™ resulted in a longer time to loss of therapeutic response than treatment with placebo. Fifty-three percent of the pregabalin-treated subjects compared to 33% of placebo patients remained on study drug and maintained a therapeutic response to Week 26 of the study. Treatment with LYRICA™ also resulted in a longer time to loss of response based on the FIQ[1], and longer time to loss of overall assessment of patient status, as measured by the PGIC[2].

1 Time to worsening of the FIQ was defined as the time to a 1-point increase from double-blind baseline in each of the subscales, and a 5-point increase from double-blind baseline evaluation for the FIQ total score.
2 Time to PGIC lack of improvement was defined as time to PGIC assessments indicating less improvement than "much improvement".

Figure 2: Time to Loss of Therapeutic Response, Fibromyalgia Study F2 (Kaplan-Meier Analysis)



Epilepsy

Pregabalin has been studied in 3 controlled clinical studies of 12-week duration with either twice a day dosing (BID) or three times a day (TID) dosing. Overall, the safety and efficacy profiles for BID and TID dosing regimens were similar.

A reduction in seizure frequency was observed by Week 1.

Generalised Anxiety Disorder

Pregabalin has been studied in 6 controlled studies of 4-6 week duration, an elderly study of 8 week duration and long-term relapse prevention study with a double blind relapse prevention phase of 6 months duration.

Relief of the symptoms of GAD as reflected by the Hamilton Anxiety Rating Scale (HAM-A) was observed by Week 1.

In controlled clinical trials (4-8 week duration) 52% of the pregabalin treated patients and 38% of the patients on placebo had at least a 50% improvement in HAM-A total score from baseline to endpoint.

Pharmacokinetic properties

LYRICA™ (pregabalin) steady-state pharmacokinetics are similar in healthy volunteers, patients with epilepsy receiving anti-epileptic drugs and patients with chronic pain.

Absorption

LYRICA™ (pregabalin) is rapidly absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥90% and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in C_{max} by approximately 25%-30% and a delay in t_{max} to approximately 2.5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution

In preclinical studies, LYRICA™ (pregabalin) has been shown to cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. In humans, the apparent volume of distribution of pregabalin following oral administration is approximately 0.56 L/kg. Pregabalin is not bound to plasma proteins.

Metabolism

LYRICA™ (pregabalin) undergoes negligible metabolism in humans. Following a dose of radiolabelled pregabalin, approximately 98% of the radioactivity recovered in the urine was unchanged pregabalin. The N-methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0.9% of the dose. In preclinical studies, there was no indication of racemisation of pregabalin S-enantiomer to the R-enantiomer.

Elimination

LYRICA™ (pregabalin) is eliminated from the systemic circulation primarily by renal excretion as unchanged drug.

Pregabalin mean elimination half-life is 6.3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance (see section **Pharmacokinetic properties**, Renal impairment).

Dosage adjustment in patients with reduced renal function or undergoing hemodialysis is necessary (see section **Posology and method of administration,** Table 1).

Linearity/non-linearity

LYRICA™ (pregabalin) pharmacokinetics are linear over the recommended daily dose range. Inter-subject pharmacokinetic variability for pregabalin is low (<20%). Multiple dose pharmacokinetics are predictable from single-dose data.

Pharmacokinetics in special patient groups

Gender

Clinical trials indicate that gender does not have a clinically significant influence on the plasma concentrations of LYRICA™ (pregabalin).

Renal impairment

LYRICA™ (pregabalin) clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by hemodialysis (following a 4-hour hemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Because renal elimination is the major elimination pathway, dosage reduction in patients with renal impairment and dosage supplementation following hemodialysis is necessary (see section **Posology and method of administration,** Table 1).

Hepatic impairment

No specific pharmacokinetic studies were carried out in patients with impaired liver function. Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged drug in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Elderly (over 65 years of age)

LYRICA™ (pregabalin) clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age-related compromised renal function (see section **Posology and method of administration,** Table 1).

Breast-feeding mothers

The pharmacokinetics of 150 mg pregabalin given every 12 hours (300 mg daily dose) was evaluated in 10 lactating women who were at least 12 weeks postpartum. Lactation had little to no influence on pregabalin pharmacokinetics. Pregabalin was excreted into breast milk with average steady-state concentrations approximately 76% of those in maternal plasma. The estimated average daily infant dose of pregabalin from breast milk (assuming mean milk consumption of 150 mL/kg/day) was 0.31 mg/kg/day, which on a mg/kg basis would be approximately 7% of the maternal dose.

Preclinical safety data

In conventional safety pharmacology studies in animals, LYRICA™ (pregabalin) was well-tolerated at clinically relevant doses. In repeated-dose toxicity studies in rats and monkeys CNS effects were observed, including hypoactivity, hyperactivity and ataxia.

An increased incidence of retinal atrophy commonly observed in aged albino rats was seen after long-term exposure to pregabalin at exposures ≥5 times the mean human exposure at the maximum recommended clinical dose.

Teratogenicity
Pregabalin was not teratogenic in mice, rats or rabbits. Foetal toxicity in rats and rabbits occurred only at exposures sufficiently above human exposure. In pre-natal/post-natal toxicity studies, pregabalin induced offspring developmental toxicity in rats at exposures >2 times the maximum recommended human exposure.

Mutagenicity
Pregabalin is not genotoxic based on results of a battery of *in vitro* and *in vivo* tests.

Carcinogenicity
Two-year carcinogenicity studies with pregabalin were conducted in rats and mice. No tumours were observed in rats at exposures up to 24 times the mean human exposure at the maximum recommended clinical dose of 600 mg/day. In mice, no increased incidence of tumours was found at exposures similar to the mean human exposure, but an increased incidence of haemangiosarcoma was observed at higher exposures. The non-genotoxic mechanism of pregabalin-induced tumour formation in mice involves platelet changes and associated endothelial cell proliferation. These platelet changes were not present in rats or in humans based on short term and limited long term clinical data. There is no evidence to suggest an associated risk to humans.

In juvenile rats the types of toxicity do not differ qualitatively from those observed in adult rats. However, juvenile rats are more sensitive. At therapeutic exposures, there was evidence of CNS clinical signs of hyperactivity and bruxism and some changes in growth (transient body weight gain suppression). Effects on the estrus cycle were observed at 5-fold the human therapeutic exposure. Neurobehavioral/cognitive effects were observed in juvenile rats 1-2 weeks after exposure >2 times (acoustic startle response) or >5 times (learning/memory) the human therapeutic exposure. Reduced acoustic startle response was observed in juvenile rats 1-2 weeks after exposure at >2 times the human therapeutic exposure. Nine weeks after exposure, this effect was no longer observable.

Storage condition

Store below 30°C.

Supply

- LYRICA™ 50 mg capsule; Box of 1 blister @ 14 capsules; Reg. No. DKIxxxxxxxxxxx
- LYRICA™ 75 mg capsule; Box of 1 blister @ 14 capsules; Reg. No. DKIxxxxxxxxxxx

- LYRICA™ 150 mg capsule; Box of 1 blister @ 14 capsules; Reg. No. DKIxxxxxxxxxxx

HARUS DENGAN RESEP DOKTER

Manufactured by:
Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

Imported by:
PT Fonko International Pharmaceuticals, Bekasi, Indonesia

Marketed by:
PT Aurogen Pharma Indonesia, Jakarta, Indonesia

Leaflet kemasan: Informasi bagi pengguna

LYRICA™ 50 mg kapsul keras
LYRICA™ 75 mg kapsul keras
LYRICA™ 150 mg kapsul keras
Pregabalin

Bacalah brosur ini dengan saksama sebelum Anda menggunakan obat ini karena mengandung informasi yang penting untuk Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan berikan kepada orang lain. Obat ini dapat membahayakan mereka, sekali pun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, berkonsultasilah dengan dokter, apoteker, atau perawat Anda. Ini termasuk segala kemungkinan efek samping yang tidak tercantum di dalam leaflet ini. Lihat bagian 8.

Apa isi leaflet ini?

1. Nama produk
LYRICA™ 50 mg kapsul keras.
LYRICA™ 75 mg kapsul keras.
LYRICA™ 150 mg kapsul keras.

2. Keterangan produk
Lyrica termasuk dalam golongan obat-obatan yang digunakan untuk mengobati epilepsi, nyeri neuropatik/nyeri pada gangguan saraf, Gangguan Kecemasan Umum/ Generalised Anxiety Disorder (GAD) pada orang dewasa dan untuk mengurangi nyeri pada penyakit fibromialgia (nyeri pada sekujur tubuh).

3. Apa kandungan di dalam obat ini?

Kapsul keras
Kapsul 50 mg: Kapsul gelatin keras berwarna putih, dengan tulisan “Pfizer” di bagian tutup kapsul dan tulisan “PGN 50” di bagian badan kapsul menggunakan tinta hitam. Badan kapsul juga ditandai dengan garis melingkar hitam.

Kapsul 75 mg: Kapsul gelatin keras berwarna putih dan oranye, dengan tulisan “Pfizer” di bagian tutup kapsul dan tulisan “PGN 75” di bagian badan kapsul menggunakan tinta hitam.

Kapsul 150 mg: Kapsul gelatin keras berwarna putih, dengan tulisan “Pfizer” di bagian tutup kapsul dan tulisan “PGN 150” di bagian badan kapsul menggunakan tinta hitam.

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

4. Kekuatan obat
50 mg; 75 mg; 150 mg.

5. Apa kegunaan obat ini?
Nyeri neuropatik perifer dan pusat: Lyrica digunakan untuk mengobati nyeri berkepanjangan yang disebabkan oleh kerusakan saraf. Berbagai penyakit bisa menyebabkan nyeri neuropatik perifer, seperti diabetes atau herpes zoster. Gambaran sensasi nyeri adalah rasa panas, terbakar, berdenyut, menyengat, menikam, tajam, kram, sakit, tertusuk, mati rasa, dan kesemutan. Nyeri neuropatik perifer dan pusat juga dapat dikaitkan dengan perubahan suasana hati, gangguan tidur, keletihan (kelelahan), dan bisa berdampak terhadap fungsi fisik dan sosial serta kualitas hidup secara keseluruhan.

Epilepsi: Lyrica digunakan untuk mengobati berbagai jenis epilepsi (kejang parsial yang disertai atau tanpa disertai generalisasi sekunder) pada orang dewasa. Dokter Anda akan meresepkan Lyrica untuk membantu mengobati epilepsi jika pengobatan Anda saat ini tidak mampu mengendalikan kondisi Anda. Anda harus meminum Lyrica di samping meminum obat yang Anda gunakan saat ini. Lyrica tidak ditujukan untuk pengobatan tunggal, tetapi harus digunakan dalam kombinasi dengan obat antiepilepsi lainnya.

Gangguan Kecemasan Umum: Lyrica digunakan untuk mengobati Gangguan Kecemasan Umum (Generalised Anxiety Disorder, GAD). Gejala GAD di antaranya adalah kecemasan dan kekhawatiran berlebihan yang berkepanjangan dan sulit dikendalikan. GAD juga bisa menimbulkan kegelisahan atau perasaan tegang atau cemas, mudah merasa letih (lelah), kesulitan untuk berkonsentrasi atau pikiran menjadi kosong, merasa mudah marah, mengalami ketegangan otot, atau gangguan tidur. Kondisi ini berbeda dengan stres dan ketegangan dalam kehidupan sehari-hari.

Fibromialgia: Lyrica digunakan untuk mengobati nyeri dalam penatalaksanaan fibromialgia (nyeri pada sekujur tubuh Anda).

6. Berapa banyak dan seberapa sering Anda seharusnya menggunakan obat ini?
Selalu minum obat ini sesuai dengan petunjuk dokter Anda. Tanyakan kepada dokter atau apoteker jika Anda merasa tidak yakin. Jangan minum obat lebih dari dosis yang diresepkan.

Dokter akan menentukan dosis yang tepat bagi Anda.

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Lyrica hanya digunakan secara oral.

Nyeri neuropatik perifer dan pusat, epilepsi, atau Gangguan Kecemasan Umum:
- Minumlah kapsul dalam jumlah yang diresepkan oleh dokter Anda.
- Dosis yang telah disesuaikan untuk Anda dan kondisi Anda, umumnya adalah antara 150 mg hingga 600 mg setiap hari.
- Dokter akan menginstruksikan Anda untuk meminum Lyrica dua atau tiga kali sehari. Untuk dosis dua kali sehari, minum Lyrica satu kali di pagi hari dan satu kali di malam hari, sekitar waktu yang sama setiap hari. Untuk dosis tiga kali sehari, minum Lyrica satu kali di pagi hari, satu kali di sore hari, dan satu kali di malam hari, sekitar waktu yang sama setiap hari.

Fibromialgia:
- Minumlah kapsul dalam jumlah yang diresepkan oleh dokter Anda.
- Dosis yang telah disesuaikan untuk Anda dan kondisi Anda, umumnya adalah antara 300 mg hingga 450 mg setiap hari.
- Dokter akan menginstruksikan Anda untuk meminum Lyrica dua kali sehari. Minum Lyrica satu kali di pagi hari dan satu kali di malam hari, sekitar waktu yang sama setiap hari.

Jika Anda merasa bahwa efek Lyrica terlalu kuat atau terlalu lemah, maka konsultasikan kepada dokter atau apoteker Anda.

Jika Anda adalah pasien lansia (berusia di atas 65 tahun), maka Anda harus meminum Lyrica secara normal kecuali jika Anda menderita gangguan ginjal.

Dokter mungkin akan meresepkan jadwal pemberian dosis dan/atau dosis yang berbeda jika Anda menderita gangguan ginjal.

Minum kapsul secara utuh dengan bantuan air.

Lanjutkan meminum Lyrica hingga dokter menginstruksikan untuk berhenti.

Jika Anda berhenti meminum Lyrica
Jangan tiba-tiba berhenti meminum Lyrica. Jika Anda ingin berhenti meminum Lyrica, konsultasikan terlebih dahulu dengan dokter Anda. Mereka akan memberi tahu Anda cara untuk melakukannya. Jika pengobatan Anda dihentikan, maka harus dilakukan secara bertahap dalam jangka waktu minimum 1 minggu.

Setelah menghentikan pengobatan dengan Lyrica untuk jangka pendek atau jangka panjang, ketahuilah bahwa Anda mungkin akan mengalami efek samping tertentu, yang disebut dengan efek putus obat. Efek samping tersebut meliputi sulit tidur, sakit kepala, mual, merasa gelisah, diare, gejala menyerupai flu, kejang, kegelisahan, depresi, nyeri, berkeringat, dan pusing. Efek ini dapat muncul lebih umum atau lebih berat jika Anda meminum Lyrica untuk jangka waktu yang lebih panjang. Jika Anda mengalami efek putus obat, Anda harus menghubungi dokter Anda.

Jika Anda memiliki pertanyaan lebih lanjut seputar penggunaan obat ini, tanyakan kepada dokter atau apoteker Anda.

7. Kapan seharusnya Anda tidak menggunakan obat ini?

Jika Anda alergi terhadap pregabalin atau bahan-bahan lainnya dalam obat ini.

Kehamilan dan menyusui
Lyrica tidak boleh diminum selama kehamilan atau saat menyusui, kecuali jika dokter menyatakan sebaliknya. Wanita usia subur harus menggunakan metode kontrasepsi yang efektif. Jika Anda hamil atau menyusui, menduga bahwa diri Anda hamil, atau sedang merencanakan kehamilan, mintalah saran dari dokter atau apoteker Anda sebelum meminum obat ini.

Mengemudi dan menggunakan mesin
Lyrica dapat menimbulkan rasa pusing, mengantuk, dan menurunnya konsentrasi. Anda dilarang mengemudi, mengoperasikan mesin yang rumit, atau terlibat dalam aktivitas berpotensi bahaya lainnya hingga Anda mengetahui apakah obat ini memengaruhi kemampuan Anda untuk menjalankan aktivitas tersebut.

Intoleransi laktosa
Jika Anda telah diberi tahu oleh dokter bahwa Anda mempunyai intoleransi terhadap jenis gula tertentu, hubungi dokter Anda sebelum meminum obat ini.

8. Efek yang tidak diinginkan
Seperti semua obat-obatan yang ada, obat ini bisa menimbulkan efek samping, meskipun tidak semua orang mengalaminya.

Efek samping yang sangat umum (kemungkinan dialami lebih dari 1 di antara 10 pasien) antara lain:
Pusing, mengantuk, sakit kepala.

Efek samping yang umum (kemungkinan dialami kurang dari 1 di antara 10 pasien) antara lain:
- Meningkatnya nafsu makan.
- Perasaan girang, bingung, disorientasi, depresi, menurunnya ketertarikan seksual, dan mudah marah.
- Gangguan perhatian, merasa canggung, gangguan memori, hilangnya memori, tremor (gemetar), kesulitan berbicara, rasa tertusuk, mati rasa, mengantuk, lesu, insomnia, kelelahan, merasa tidak normal.
- Penglihatan kabur, pandangan ganda.
- Vertigo, gangguan keseimbangan, terjatuh.
- Mulut kering, konstipasi, muntah, kembung, diare, mual, pembengkakan abdomen.
- Pembengkakan badan, termasuk anggota gerak.
- Merasa mabuk, gaya berjalan tidak normal.
- Penambahan berat badan.
- Kram otot, nyeri sendi, nyeri punggung, nyeri tungkai.
- Tenggorokan sakit.

Efek samping yang tidak umum (kemungkinan dialami kurang dari 1 di antara 100 pasien) antara lain:
- Hilangnya nafsu makan, penurunan berat badan, gula darah rendah, gula darah tinggi.
- Perubahan persepsi terhadap diri, gelisah, agitasi, perubahan suasana hati, halusinasi, mimpi tidak normal, suasana hati yang meninggi, gangguan mental, kesulitan berpikir,

peningkatan ketertarikan seksual, gangguan fungsi seksual termasuk ketidakmampuan untuk mencapai klimaks seksual, keterlambatan ejakulasi.

- Perubahan penglihatan, gerakan mata yang tidak biasa, perubahan penglihatan termasuk penglihatan terowongan, penglihatan silau, gerakan menyentak, penurunan refleks, peningkatan aktivitas, pusing saat berdiri, kulit sensitif, sensasi terbakar, tremor saat bergerak, penurunan kesadaran, hilangnya kesadaran, pingsan, peningkatan sensitivitas terhadap kebisingan, merasa tidak sehat.
- Mata kering, pembengkakan mata, nyeri pada mata, mata lemah, mata berair, iritasi mata.
- Gangguan irama jantung, peningkatan denyut jantung, tekanan darah rendah, tekanan darah tinggi, perubahan denyut jantung.
- Pipi memerah, semburan panas.
- Kesulitan bernapas, hidung tersumbat.
- Produksi air liur meningkat, nyeri ulu hati, mati rasa di sekitar mulut.
- Kesulitan ereksi.
- Berkeringat, ruam, menggigil, demam.
- Kedutan otot, pembengkakan sendi, kekakuan sendi, nyeri termasuk nyeri otot, nyeri leher.
- Kesulitan berkemih atau nyeri saat berkemih, inkontinensia (berkemih tanpa disadari).
- Lemah, haus, dada sesak.
- Perubahan hasil tes darah dan hati (peningkatan alanin amino transferase, peningkatan aspartat aminotransferase, penurunan jumlah platelet, neutropenia, peningkatan kreatinin darah, penurunan kalium darah).
- Hipersensitivitas, pembengkakan wajah, rasa gatal, kaligata (ruam merah, gatal dan bentol di kulit), pilek, mimisan, batuk, mendengkur.
- Nyeri haid.
- Tangan dan kaki terasa dingin.

Efek samping yang jarang (kemungkinan dialami kurang dari 1 di antara 1000 pasien) antara lain:

- Serangan panik, apatis,
- Kesulitan memilih kata, indera penciuman tidak normal, penglihatan berayun, perubahan persepsi kedalaman, penglihatan silau, hilangnya pengecapan.
- Pupil melebar, mata juling.
- Keringat dingin, tenggorokan terasa sesak, hidung kering, pembengkakan lidah.
- Peradangan pankreas.
- Kesulitan menelan.
- Nyeri payudara.
- Gerakan badan melambat atau berkurang.
- Kesulitan menulis dengan baik.
- Peningkatan cairan di dalam abdomen.
- Cairan di dalam paru-paru.
- Gagal jantung
- Kerusakan otot.
- Keluar cairan dari payudara, pertumbuhan payudara tidak normal, pertumbuhan payudara pada laki-laki.
- Periode haid terganggu.
- Gagal ginjal, penurunan volume urin, retensi air seni.
- Penurunan jumlah sel darah putih, peningkatan kreatinin fosfokinase darah.

- Perilaku yang tidak patut.
- Reaksi alergi yang dapat meliputi kesulitan bernapas, peradangan mata (keratitis), dan reaksi kulit serius yang ditandai dengan bercak kemerahan tanpa tonjolan berbentuk lingkaran atau seperti target pada torso, sering kali dengan lepuh di bagian tengah, kulit mengelupas, bisul di mulut, tenggorokan, hidung, alat kelamin, dan mata. Ruam kulit yang serius ini dapat didahului oleh demam dan gejala menyerupai flu (Sindrom Stevens-Johnson).

Jika Anda mengalami pembengkakan wajah atau lidah atau jika kulit Anda memerah dan mulai melepuh atau mengelupas, Anda harus segera meminta pertolongan medis.

Efek samping tertentu mungkin lebih umum terjadi, seperti perasaan mengantuk, karena pasien dengan cedera sumsum tulang belakang mungkin juga meminum obat-obatan lain untuk mengobati, misalnya, nyeri atau kelenturan, yang memiliki efek serupa dengan Pregabalin dan tingkat keparahan efek ini dapat meningkat jika diminum bersamaan.

Melaporkan efek samping
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. Anda dapat melaporkan efek samping tersebut melalui pv@dexagroup.com dan pharmacovigilance.id@aurobindo.com. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lebih lanjut mengenai keamanan obat ini.

9. Apa saja obat atau makanan lain yang harus dihindari selama menggunakan obat ini?
Lyrica dan obat-obatan tertentu lainnya dapat saling memengaruhi satu sama lain (interaksi). Jika diminum bersama obat-obatan tertentu lainnya yang menurunkan aktivitas otak (termasuk opioid), Lyrica dapat memperkuat efek samping yang berhubungan dengan obat-obatan ini, dan dapat menyebabkan gagal napas, koma, dan kematian. Derajat rasa pusing, rasa mengantuk, dan penurunan konsentrasi dapat meningkat jika Lyrica diminum bersamaan dengan obat-obatan yang mengandung:

Oksikodon – (digunakan sebagai pereda nyeri)
Lorazepam – (digunakan untuk mengobati kecemasan)
Alkohol

Lyrica dapat diminum bersama pil kontrasepsi.

Lyrica dengan makanan, minuman, dan alkohol
Kapsul Lyrica dapat diminum setelah atau sebelum makan.

Disarankan untuk tidak mengonsumsi alkohol selama meminum Lyrica.

10. Apa yang harus dilakukan jika ada dosis terlewat?
Penting kiranya untuk meminum kapsul Lyrica Anda secara teratur pada waktu yang sama setiap hari. Jika Anda lupa meminum satu dosis, segera minum saat Anda ingat kecuali jika sudah masuk waktu untuk dosis berikutnya. Jika kondisi ini terjadi, tetap lanjutkan dosis berikutnya seperti biasa. Jangan meminum dosis ganda untuk mengejar dosis yang terlupa.

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

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Jangan gunakan obat ini jika sudah melewati tanggal kedaluwarsanya. Tanggal kedaluwarsa mengacu pada hari terakhir dari bulan yang tertera.

Simpan pada suhu di bawah 30 °C.

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

12. Tanda-tanda dan gejala-gejala overdosis
Anda mungkin merasa mengantuk, bingung, agitasi, atau gelisah karena meminum Lyrica melebihi dosis yang seharusnya. Telah dilaporkan juga terjadinya kejang.

13. Apa yang harus dilakukan jika Anda menggunakan lebih dari dosis yang dianjurkan?
Hubungi dokter Anda atau segera datangi unit gawat darurat di rumah sakit terdekat. Bawa dus atau botol kapsul Lyrica bersama Anda.

14. Apa saja yang perlu diperhatikan saat menggunakan obat ini?
Peringatan dan Tindakan Pencegahan
Konsultasikan dengan dokter atau apoteker Anda sebelum meminum Lyrica.

- Beberapa pasien yang meminum Lyrica telah melaporkan gejala-gejala yang mengarah ke reaksi alergi. Gejala-gejala ini meliputi pembengkakan wajah, bibir, lidah, dan tenggorok serta ruam kulit yang merata. Jika Anda mengalami salah satu dari reaksi ini, segera hubungi dokter Anda.

- Lyrica juga dikaitkan dengan pusing dan somnolen, yang dapat meningkatkan kejadian cedera tidak disengaja (terjatuh) pada pasien lansia. Oleh karena itu, Anda harus berhati-hati hingga Anda terbiasa dengan efek yang mungkin ditimbulkan oleh obat ini.

- Lyrica dapat menyebabkan penglihatan kabur atau perubahan penglihatan lainnya, yang kebanyakan bersifat sementara. Anda harus segera memberi tahu dokter jika Anda mengalami perubahan penglihatan apa pun.

- Beberapa pasien dengan diabetes yang mengalami kenaikan berat badan saat meminum pregabalin mungkin perlu mengubah obat diabetesnya.

- Efek samping tertentu mungkin lebih umum terjadi, seperti perasaan mengantuk, karena pasien dengan cedera sumsum tulang belakang mungkin juga meminum obat-obatan lain untuk mengobati, misalnya, nyeri atau kelenturan, yang memiliki efek serupa dengan Pregabalin dan tingkat keparahan efek ini dapat meningkat jika diminum bersamaan.

- Terdapat laporan adanya gagal jantung pada beberapa pasien saat meminum Lyrica; pasien-pasien ini sebagian besar adalah pasien lansia dengan masalah kardiovaskular. **Sebelum meminum obat ini, Anda harus memberi tahu dokter Anda jika memiliki riwayat penyakit jantung**.

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- Terdapat laporan terjadinya gagal ginjal pada beberapa pasien saat meminum Lyrica. Jika saat meminum Lyrica Anda mengalami penurunan jumlah berkemih, Anda harus memberi tahu dokter Anda karena penghentian obat dapat meredakan kondisi ini.

- Jika Lyrica diminum bersama obat-obatan lain yang dapat menyebabkan konstipasi (seperti beberapa jenis obat-obatan pereda nyeri), bisa jadi akan memunculkan masalah gastrointestinal (misalnya konstipasi, sumbatan usus, atau kelumpuhan usus). Beri tahu dokter jika Anda mengalami konstipasi, khususnya jika Anda rentan mengalami masalah ini.

Ketergantungan

Beberapa orang dapat menjadi ketergantungan pada Lyrica (kebutuhan untuk tetap minum obat). Mereka mungkin mengalami efek putus obat ketika berhenti meminum Lyrica (lihat bagian **Jika Anda berhenti meminum Lyrica**). Jika khawatir bahwa Anda mungkin menjadi ketergantungan pada Lyrica, penting bagi Anda untuk berkonsultasi dengan dokter Anda.

Jika Anda mengamati tanda-tanda berikut saat meminum Lyrica, itu bisa jadi tanda bahwa Anda telah menjadi ketergantungan:
- Anda perlu meminum obat lebih lama daripada yang dianjurkan oleh pemberi resep
- Anda merasa perlu meminum lebih banyak daripada dosis yang dianjurkan
- Anda meminum obat untuk alasan selain dari yang diresepkan
- Anda telah berulang kali gagal mencoba berhenti atau mengontrol konsumsi obat
- Anda merasa tidak enak badan ketika berhenti meminum obat, dan Anda merasa lebih baik setelah meminum obat lagi

Jika Anda mengamati salah satu tanda tersebut, hubungi dokter Anda untuk mendiskusikan jalur pengobatan terbaik bagi Anda, termasuk kapan waktu yang tepat untuk berhenti dan bagaimana melakukannya dengan aman.

15. Kapan sebaiknya Anda berkonsultasi dengan dokter?
Jika Anda memiliki pertanyaan lebih lanjut atau Anda mengalami situasi yang sama seperti yang tercantum dalam leaflet ini, konsultasikan dengan dokter, apoteker, atau perawat Anda.

16. Nama/logo produsen/importir/Pemegang Hak Pemasaran
LYRICA™ 50 mg kapsul; Dus berisi 1 blister @ 14 kapsul; No. Reg. DKIxxxxxxxxxxx
LYRICA™ 75 mg kapsul; Dus berisi 1 blister @ 14 kapsul; No. Reg. DKIxxxxxxxxxxx
LYRICA™ 150 mg kapsul; Dus berisi 1 blister @ 14 kapsul; No. Reg. DKIxxxxxxxxxxx

HARUS DENGAN RESEP DOKTER

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17. Tanggal revisi PIL

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