

LYRICA® CR TABLETS

Pregabalin (82.5 mg, 165 mg Tablets)

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What LYRICA CR is used for

LYRICA CR is indicated for the management of:

- Pain caused by nerve damage (neuropathic pain) due to diabetes
- Ongoing nerve pain after shingles (postherpetic neuralgia)

How LYRICA CR works

LYRICA CR helps decrease the number of nerve signals, and as a result calms down overly sensitive nerve cells.

Before you use LYRICA CR

- When you must not use it

Do not start taking LYRICA CR if you are allergic to pregabalin or any of the ingredients in LYRICA CR. See the end of this leaflet for a complete list of ingredients in LYRICA CR.

Symptoms of an allergic reaction to LYRICA CR may include:

- Serious, even life-threatening allergic reactions
- Suicidal thoughts or actions
- Swelling of your hands, legs and feet
- Dizziness and sleepiness

Pregnancy and lactation

Animal studies have shown that pregabalin, the active ingredient in

LYRICA CR, causes reproductive toxicity. Hence it should not be taken during pregnancy. Effective contraception must be used in women of child bearing potential.

LYRICA CR is excreted in the milk of lactating women. As the safety of LYRICA CR in infants is not known, breast-feeding is not recommended during treatment with LYRICA CR. You and your healthcare provider should discuss whether you should take LYRICA CR or breast-feed, but you should not do both.

- Before you start to take it

Tell your healthcare provider about all your medical conditions including if you:

- have or had depression, mood problems or suicidal thoughts or behavior
- have kidney problems or get kidney dialysis
- have heart problems including heart failure
- have a bleeding problem or a low blood platelet count
- have abused prescription medicines, or street drugs in the past
- have ever had swelling in your face, mouth (tongue, lips, gums) and neck (throat and larynx; angioedema)
- are in the first trimester of pregnancy as LYRICA CR may cause major birth defects in the unborn child.
- have or had indigestion to milk or milk products (lactose intolerance)
- have brain malfunction (encephalopathy)
- have had cases of misuse, abuse and dependence (drug-seeking behavior) in the past
- are undergoing treatment of central neuropathic pain due to spinal cord injury
- have existing slow and ineffective

breathing, or if you are taking a group of medicines called CNS depressants, including opioids.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins or herbal supplements. LYRICA CR and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- Angiotensin converting enzyme (ACE) inhibitors, which are used to treat many conditions, including high blood pressure. You may have a higher chance for swelling and hives if these medicines are taken with LYRICA CR. See Section 5 “While you are using LYRICA CR”.
- Avandia (rosiglitazone), Avandamet (contains rosiglitazone and metformin), or Actos (pioglitazone) for diabetes. You may have a higher chance of weight gain or swelling of your hands or feet if these medicines are taken with LYRICA CR. See Section 6. “Side Effects”.
- Any medicines that make you sleepy.
- LYRICA CR may increase the effects of ethanol and lorazepam.
- LYRICA CR appears to increase certain effects (impairment of thought process and gross bodily movements) caused by oxycodone.
- There are reports of lung failure, coma and deaths in patients taking LYRICA CR and other central nervous system depressant medications, including in patients who are drug abusers.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and

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pharmacist each time you get a new medicine. Do not start a new medicine without talking to your healthcare provider.

How to use LYRICA CR

- How much to use

- Take LYRICA CR exactly as prescribed. Your healthcare provider will tell you how much LYRICA CR to take.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.

- Pain caused by nerve damage (neuropathic pain) due to diabetes

- Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability. The maximum recommended dose of LYRICA CR is 330 mg once daily.

- Ongoing nerve pain after shingles (postherpetic neuralgia)

- Begin dosing at 165 mg once daily and increase to 330 mg once daily within 1 week based on individual patient response and tolerability.

- Patients who do not experience sufficient pain relief following 2 to 4 weeks of treatment with 330 mg once daily and who are able to tolerate LYRICA CR, may be treated with up to 660 mg once daily.

- When to use it

Take LYRICA CR exactly as prescribed. Your healthcare provider will tell you when to take LYRICA CR. It is advised to take LYRICA CR at the same time each day.

- How long to use it

Do not stop taking LYRICA CR without checking with your healthcare provider. If you stop taking LYRICA CR suddenly, you may have trouble sleeping, nausea, headaches, anxiety, and diarrhea. If you have epilepsy and you stop taking LYRICA CR suddenly, you may have seizures more often. If LYRICA CR is discontinued, taper the drug gradually over a minimum of 1 week rather than discontinue the drug abruptly. Talk with your healthcare provider about how to stop LYRICA CR slowly.

- If you forget to use it

If you miss a dose after an evening meal, take it prior to bedtime following a snack. If you miss a dose prior to bedtime, take the next dose following a morning meal. If you miss a dose following the morning meal, take the next dose at the usual time that evening following an evening meal.

- If you use too much (overdose)

If you take too much LYRICA CR, call your healthcare provider or poison control center, or go to the nearest emergency room right away.

These side effects were reported when LYRICA CR was taken too much:
Affective disorder (abnormal disturbances of mood), sleepiness, confusion, depression, agitation and restlessness.

Fits (seizures) were also reported when the medicine was taken in overdose.

While you are using LYRICA CR

- Things you must do

Stop taking LYRICA CR and

call your healthcare provider immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Trouble breathing
- Rash, hives (raised bumps) or blisters

Call your healthcare provider immediately if you have any of these symptoms, especially if they are new, worse or worry you:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

- Things you must not do

- Do not drive a car, work with machines, or do other dangerous activities until you know how LYRICA CR affects you.

Pregabalin may cause dizziness and extreme sleepiness which may impair the ability to perform tasks such as driving or operating machinery and could increase the occurrence of accidental injury (fall) in the elderly population.

Ask your healthcare provider about when it will be okay to do these activities.

- Things to be careful of

If you have suicidal thoughts or actions, do not stop LYRICA CR

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without first talking to a healthcare provider.

- Stopping LYRICA CR suddenly can cause serious problems
- Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Side Effects

Very Common:

- Dizziness, sleepiness
- Headache

Common:

- Cold
- Increased appetite
- Elevated mood, confused state, irritability, depression, loss in sense of direction, inability to sleep, reduced sex drive
- Lack of voluntary coordination of muscle, loss in control of posture, muscle contraction, loss of memory, memory impairment, disturbance in attention, abnormal tingling and pricking sensation, reduced sense of touch, relaxed state/reduction of irritability or agitation, balance disorder, lack of energy
- Blurry vision and double vision
- Loss of balance
- Vomiting, constipation or hard bowels, accumulation of gas in alimentary canal, accumulation of

gas or air in the abdomen, dry mouth

- Muscle cramp, joint pain, back pain, pain in the limbs, tightening of muscles
- Accumulation of fluid in tissues, abnormal walking, fall, feeling drunk, feeling abnormal, weakness
- Increased weight
- Diarrhea, vomiting

Rare:

- Stevens-Johnson syndrome

If you have diabetes, you should pay attention to your skin while taking LYRICA CR

and tell your healthcare provider about any sores or skin problems.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of LYRICA CR. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers→Reporting Medicinal Problems/Side Effects/AEFI).

Storage and Disposal of LYRICA CR

- Storage

Store LYRICA CR tablets below 25°C. Keep in a cool, dry place away from sunlight.

- Disposal

Safely throw away any LYRICA CR that is out of date or no longer needed.

Keep LYRICA CR and all medicines out of the reach of children.

Product Description

- What it looks like

82.5 mg tablets :
Light blue, film-coated, almond-shaped tablet debossed with “VLE” on 1 side and “PGN 82.5” on the other side.

165 mg tablets :
Beige, film-coated, almond-shaped tablet debossed with “VLE” on 1 side and “PGN 165” on the other side.

- Ingredients

- Active ingredient
Pregabalin
- Inactive ingredients
Kollidon SR, Crospovidone (Polyplasdone XL), Polyethylene Oxide (WSR N-60K LEO), Polyethylene Oxide (WSR N-12K LEO), Carbomer Homopolymer Type A (Carbopol 71G), Magnesium Stearate and Purified Water.

In 82.5 mg tablet: Opadry® II Complete Film Coating System 85F105027 Blue; contains Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol 3350, Indigo Carmine Aluminium Lake

In 165 mg tablet: Opadry® II Complete Film Coating System 85F170009 Beige; contains Polyvinyl Alcohol, Talc, Titanium Dioxide, Macrogol 3350, Iron Oxide Yellow, Iron Oxide Red

- MAL number:

LYRICA CR 82.5 mg Tablets -

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MAL25046010ACRZ
LYRICA CR 165 mg Tablets -
MAL25046011ACRZ

Manufacturer

Pfizer Manufacturing Deutschland
GmbH
Mooswaldallee 1
Freiburg Im Breisgau
Germany

Product Registration Holder

Viatris Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

Date of Revision

20/05/2025

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NPRA (R1)24/041

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