

LEPTICA CAPSULE

Pregabalin (150 mg)

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What LEPTICA is used for

LEPTICA is used to treat:

Neuropathic pain

Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

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

Generalized anxiety disorder

Pregabalin is indicated for the treatment of generalized anxiety disorder (GAD) in adults.

Fibromyalgia

Pregabalin is indicated for the management of fibromyalgia.

How LEPTICA works

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

Before you use LEPTICA

-When you must not use it

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

Symptoms of an allergic reaction to LEPTICA 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 LEPTICA causes reproductive toxicity. Hence it should not be taken during pregnancy. Effective contraception must be used in women of child bearing potential.

LEPTICA is excreted in the milk of lactating women. As the safety of LEPTICA in infants is not known, breastfeeding is not recommended during treatment with LEPTICA. You and your healthcare provider should discuss whether you should take LEPTICA or breastfeed, but you should not do both.

-Before you start to use 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 LEPTICA 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. LEPTICA 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 LEPTICA. See Section 5 "While you are using LEPTICA".
- 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 LEPTICA. See section 6 "Side Effects".
- Any medicines that make you sleepy.
- LEPTICA may increase the effects of ethanol and lorazepam.
- LEPTICA 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 LEPTICA and other central nervous system depressant

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

How to use LEPTICA

-How much to use

- Take LEPTICA exactly as prescribed. Your healthcare provider will tell you how much LEPTICA to take.
- LEPTICA may be taken with or without food.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- The dose range is 150 to 600 mg per day given in either two or three divided doses.

-When to use it

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

-How long to use it

Do not stop taking LEPTICA without checking with your healthcare provider. If you stop taking LEPTICA suddenly, you may have trouble sleeping, nausea, headaches, anxiety, excessive sweating, and diarrhea. If you have epilepsy and you stop taking LEPTICA suddenly, you may have seizures more often. If LEPTICA 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 LEPTICA slowly.

-If you forget to use it

If you miss a dose, take it as soon as you remember. If it is almost time for

your next dose, just skip the missed dose. Take the next dose at your regular time. Do not take two doses at the same time.

-If you use too much (overdose)

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

These side effects were reported when LEPTICA 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.

If you have any further questions about this medicine, ask your doctor or nurse.

While you are using it

-Things you must do

Stop taking LEPTICA 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 LEPTICA 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 LEPTICA without first talking to a healthcare provider.

- Stopping LEPTICA 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.

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

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

These are not all the possible side effects of LEPTICA. 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.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of LEPTICA

-Storage

Store LEPTICA capsules at temperatures below 30°C.

-Disposal

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

Keep LEPTICA and all medicines out of the reach of children.

Product description

-What it looks like

Hard gelatin capsule, body and cap white op (44.700), contain white crystalline powder. Cap printed DXM logo in black, body unmark.

-Ingredients

- Active Ingredient:
Pregabalin
- Inactive Ingredients:
Spray dried lactose DCL 11, corn starch, talc, capsule shell size 2 (body and cap white op. (44.700)).

-MAL Numbers

MALXXXXXXXXXX

Manufacturer

PT Dexa Medica
Jl. Jend. Bambang Utoyo No. 138
Palembang-Indonesia.

Product Registration Holder

Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
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