

LEAFLET PREGADEX CAPSULES

Pregadex®

Pregadex 75 mg
Pregadex 150mg
Pregadex 300 mg
Pregabalin

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT PREGADEX IS AND WHAT IT IS USED FOR

Pregadex belongs to a group of medicines used to treat epilepsy, neuropathic pain and Generalized Anxiety Disorder (GAD) in adults.

Peripheral and central neuropathic pain: Pregadex is used to treat long lasting pain caused by damage to the nerves. A variety of diseases can cause peripheral neuropathic pain, such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles. Peripheral and central neuropathic pain may also be associated with mood changes, sleep disturbance, fatigue (tiredness), and can have an impact on physical and social functioning and overall quality of life.

Epilepsy: Pregadex is used to treat a certain form of epilepsy (partial seizures with or without secondary generalization) in adults. Your doctor will prescribe Pregadex for you to help treat your epilepsy when your current treatment is not controlling your condition. You should take Pregadex in addition to your current treatment. Pregadex is not intended to be used alone, but should always be used in combination with other anti-epileptic treatment.

Generalized Anxiety Disorder: Pregadex is used to treat Generalized Anxiety Disorder (GAD). The symptoms of GAD are prolonged excessive anxiety and worry that are difficult to control. GAD can also cause restlessness or feeling keyed up or on edge, being easily fatigued (tired), having difficulty concentrating or mind going blank, feeling irritable, and having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

2. BEFORE YOU TAKE Pregadex

Do not take Pregadex

If you are allergic (hypersensitive) to pregabalin or any of the other ingredients of Pregadex.

Take special care with Pregadex

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, pregabalin should not be used in this age group.

- Some patients taking pregabalin have reported symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- Pregadex has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in elderly patients. Therefore, you should be careful until you are used to any effect the medicine might have.
- Pregadex may cause blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- Some patients with diabetes who gain weight while taking Pregadex may need an alteration in their diabetic medicines.
- Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregadex and the severity of these effects may be increased when taken together.
- There have been reports of heart failure in some patients when taking pregabalin; these patients were mostly elderly with cardiovascular conditions. **Before taking this medicine you should tell your doctor if you have a history of heart disease.**
- There have been reports of kidney failure in some patients when taking pregabalin. If while taking Pregadex you notice decreased urination, you should tell your doctor as soon as you notice the medicine may improve this.
- A small number of people being treated with anti-epileptics such as Pregadex have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When Pregadex is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralyzed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- Before taking this medicine you should tell your doctor if you have a history of alcoholism or drug dependence. Let your doctor know if you think you need more medicine than prescribed.
- There have been reports of convulsions when taking pregabalin or shortly after stopping pregabalin. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking pregabalin when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.
- This medicine has been associated with serious, life-threatening, and fatal respiratory depression. The risk may be increased with the concomitant use of opioids and other central nervous system (CNS) depressants, and with conditions such as chronic obstructive pulmonary disease. The elderly is also at higher risk. Your doctor should advise you to start pregabalin at the lowest dose and monitor your symptoms of respiratory depression and sedation when you are taking an opioid or other CNS depressants (eg, benzodiazepines). If you have an underlying respiratory disease or you are an elderly patient, you are also at increased risk and should be managed similarly.

Taking other medicines

Before taking any new medicine with Pregadex you should talk to your doctor. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregadex and certain other medicines may influence each other (interaction). When taken with certain other medicines, Pregadex may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregadex is taken together with medicinal products containing:

- Oxycodone (used as a pain-killer)
- Lorazepam (used for treating anxiety).
- Alcohol.

Opioids and CNS depressants

Serious respiratory depression may occur with pregabalin when co-administered with opioids and CNS depressants such as benzodiazepine. Therefore, your doctor should monitor you for symptoms of respiratory depression and sedation if you require concomitant treatment with opioids or CNS depressants. Pregadex may be taken with oral contraceptives.

Taking Pregadex with food and drink

Pregadex capsules may be taken with or without food.

It is advised not to drink alcohol while taking Pregadex

Pregnancy and breast-feeding

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the medicine you are taking might pose to your unborn baby.

- If you are planning to become pregnant you should discuss your treatment with your doctor as early as possible before you become pregnant.
- You should not stop your treatment without discussing this with your doctor.

Pregnancy

Pregabalin should not be taken during pregnancy or when breast-feeding, unless you are told otherwise by your doctor. Effective contraception must be used by women of child-bearing potential.

There has been limited research specifically looking at the use of pregabalin in pregnant women.

A recent study suggested that women who took pregabalin while they were pregnant might have a slightly higher chance of having a baby born with physical birth abnormalities. More research is needed to better understand and inform on the safety of use of pregabalin during pregnancy and whether it is associated with an increased risk of harm to the unborn child.

Breast-feeding

Pregabalin passes into breastmilk and should not be taken during breastfeeding unless you are told otherwise by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Pregadex may produce dizziness, sleepiness and decreased concentration. You should not drive, operate complex machinery or engage in other potentially hazardous activities until you know whether this medicine affects your ability to perform these activities.

Important information about some of the ingredients of Pregadex:

Pregadex contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE Pregadex

Always take Pregadex exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine what dose is appropriate for you.

Peripheral and central neuropathic pain, epilepsy or Generalized Anxiety Disorder:

Take the number of capsules as instructed by your doctor.

The dose, which has been adjusted for you and your condition, will generally be between 150 mg and 600 mg each day.

Your doctor will tell you to take Pregadex either twice or three times a day. For twice a day take Pregadex once in the morning and once in the evening, at about the same time each day. For three times a day take Pregadex once in the morning, once in the afternoon and once in the evening, at about the same time each day.

If you have the impression that the effect of Pregadex is too strong or too weak, talk to your doctor or pharmacist.

If you are an elderly patient (over 65 years of age), you should take Pregadex normally except if you have problems with your kidneys.

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

Swallow the capsule whole with water.

Continue taking Pregadex until your doctor tells you to stop.

If you take more Pregadex than you should

Call your doctor or go to the nearest hospital emergency unit immediately. Take your box of Pregadex capsules with you. You may feel sleepy, confused, agitated or restless as a result of taking more Pregadex than you should.

If you forget to take Pregadex

It is important to take your Pregadex capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Pregadex

Do not stop taking Pregadex unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week. If you have any further questions on the use of this product, ask your doctor or pharmacist. After stopping long and short-term pregabalin treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. It is not clear at this time whether these symptoms occur more commonly or severely if you have been taking pregabalin for a longer period of time.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pregadex can have side effects, although not everyone gets them.

Very common side-effects (≥1/10):

- Dizziness, tiredness.

Common side-effects (<1/10 and ≥ 1/100):

- Increased appetite.
- Feeling of elation, confusion, disorientation, changes in sexual interest, irritability.
- Disturbance in attention, clumsiness, memory impairment, tremor, difficulty with speaking, tingling feeling, sedation, lethargy, insomnia, fatigue.
- Blurred vision, double vision.
- Vertigo, problems with balance.
- Dry mouth, constipation, vomiting, and flatulence.
- Difficulties with erection.
- Swelling of the body including extremities.
- Feeling drunk, abnormal style of walking.
- Weight gain.

Uncommon side-effects (<1/100 and ≥1/1000):

- Loss of appetite, low blood sugar.
- Change in perception of self, restlessness, depression, agitation, mood swings, difficulty finding words, loss of memory, hallucinations, abnormal dreams, panic attacks, apathy, feeling abnormal, problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.
- Difficulty with thinking, numbness, changes in eyesight, unusual eye movement, jerky movements, reduced reflexes, increased activity, dizziness on standing, sensitive skin, loss of taste, burning sensation, tremor on movement, decreased consciousness, fainting, increased sensitivity to noise.
- Dry eyes, eye swelling, eye pain, weak eyes, and watery eyes.
- Heart rhythm disturbances, increased heart rate, low blood pressure, high blood pressure.
- Flushing, hot flushes.
- Difficulty breathing, sore throat, dry nose.
- Swollen abdomen, increased saliva production, heartburn, numb around mouth.
- Sweating, rash, chills.
- Muscle twitching, joint swelling, muscle cramp, muscle stiffness, pain including muscle pain, joint pain, back pain, pain in limb.
- Difficulty with or painful urination, incontinence.
- Weakness, fall, thirst, chest tightness.
- Changes in blood and liver test results (blood creatinine phosphokinase increased, alanine amino transferase increased, aspartate aminotransferase increased, platelet count decreased).

Rare side-effects (<1/1000):

- Changes in heart beat.
- Coldness of hands and feet.
- Cough, nasal congestion, runny nose, nose bleed, snoring.
- Abnormal sense of smell, changes in vision including tunnel vision, swinging vision, altered perception of depth, flashes of light, visual brightness.
- Dilated pupils, cross eyes, eye irritation.
- Fever, cold sweat, tightness of the throat.
- Inflammation of the pancreas.
- Difficulty in swallowing.
- Slow or reduced movement of the body.
- Difficulty with writing properly.
- Hives.
- Increased fluid in the abdomen.
- Muscle damage.
- Neck pain.
- Breast pain, breast discharge, abnormal breast growth, painful or interrupted menstrual periods.
- High blood sugar.
- Weight loss.
- Elevated mood.
- Kidney failure, reduced urine volume.
- Changes in blood test results (decrease in blood potassium, increase in blood creatinine, decrease in white blood cell count including neutrophils).
- Inappropriate behavior.

Additional reactions reported from post marketing experience include heart failure, changes in the recording of electrical changes (ECG) in the heart which correspond to heart rhythm disturbances, fluid in the lungs, loss of consciousness, convulsions, hypersensitivity and allergic reactions (which may include swollen face, swollen tongue, difficulty breathing, itchiness, inflammation of the eyes (keratitis), vision loss and a serious skin reaction characterized by rash, blisters, peeling skin and pain), mental impairment, aggression, urinary retention, diarrhea, headache, nausea, and feeling unwell.

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel you should seek immediate medical advice.

Certain side effects may be more common, such as sleepiness, because patients with spinal cord injury may be taking other medicines to treat, for example, pain or spasticity, that have similar side effects to Pregabalin and the severity of these effects may be increased when taken together.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Pregadex

Do not store above 30°C.

Keep out of the reach and sight of children.

6. FURTHER INFORMATION

What Pregadex contains?

The active substance: pregabalin. Each hard capsule contains 75 mg, 150 mg or 300 mg pregabalin.

The other ingredients: Lactose, Starch, Purified Talc, Gelatin.

What Pregadex looks like and the contents of the pack:

Pregadex 75mg capsules is size no. 3, hard gelatin capsule with opaque light yellow to yellow cap and body containing a white to off white powder. The capsule is printed with "PREGADEX 75mg" on the both parts.

Pregadex 150mg capsules is size no. 2, hard gelatin capsule with opaque orange cap and body containing a white to off white powder. The capsule is printed with "PREGADEX 150mg" on the both parts.

Pregadex 300mg capsules is size no. "0el", hard gelatin capsule with opaque light brown cap and body containing a white to off white powder. The capsule is printed with "PREGADEX 300mg" on the both parts.

Each pack contains 30 capsules.

Marketing Authorisation Holder and Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant

Saudi Arabia

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"Pregadex" is a trade mark
34PGA36

To report any side effect(s):

For Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- SFDA call center: 19999
- E-mail: npc.drug@sFDA.gov.sa
- Website: <https://ade.sfda.gov.sa>

For UAE

- Pharmacovigilance & Medical Device section
 - P.O.Box: 1853
 - Tel: 80011111
 - Email: pv@mohap.gov.ae
 - Drug Department, Ministry of Health & Prevention, Dubai, UAE.
- For Oman**
- Department of Pharmacovigilance & Drug Information
 - Directorate General of Pharmaceutical Affairs & Drug Control
 - Ministry of Health, Sultanate of Oman
 - Phone Nos. 22357687 / 22357686
 - Fax: 22358489
 - Email: dg-padc@moh.gov.om
 - Website: www.moh.gov.om

For Jordan

- JFDA's site: Jfda.com
- JFDA PV email: jpc@jfda.jo
- JFDA reporting link: <https://primaryreporting.who.unc.org/JO>
- Phone: +962-6-5632000
- QR code



This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists