

PREZEL 75 (PREGABALIN CAPSULES 75MG)

PREZEL 150 (PREGABALIN CAPSULES 150MG)

Pregabalin Capsules 75mg/150mg

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What *Prezel* is used for

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

Peripheral and central neuropathic pain:

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

Generalised Anxiety Disorder: *Prezel* is used to treat Generalised 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, having muscle tension or sleep disturbance. This is different to the stresses and strains of everyday life.

Fibromyalgia: *Prezel* is used to treat fibromyalgia. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory and mood issues.

How *Prezel* works

Pregabalin, the active substance in *Prezel*, belongs to antiepileptic drugs. It works by slowing impulses across the brain that are involved in development of epilepsy, neuropathic pain and generalized anxiety disorder.

Before you use *Prezel*

- When you must not use it

If you are allergic to pregabalin or any of the other ingredients of this medicine

Pregnancy and lactation

Prezel 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. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Before you start use it

Talk to your doctor or pharmacist before taking *Prezel*.

- Some patients taking *Prezel* 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.

- *Prezel* 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.

- *Prezel* 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 pregabalin 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 Pregabalin and the severity of these effects may be increased

when taken together.

- There have been reports of heart failure in some patients when taking *Prezel*; 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 *Prezel*. If while taking *Prezel* you notice decreased urination, you should tell your doctor as stopping the medicine may improve this.
- A small number of people being treated with anti-epileptics such as *Prezel* have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- When *Prezel* 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 paralysed 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 any drug abuse or dependence. Do not take more medicine than prescribed.
- There have been reports of convulsions when taking *Prezel* or shortly after stopping *Prezel*. If you experience a convulsion, contact your doctor immediately.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking *Prezel* when they have other conditions. Tell your doctor if you have a history of any serious medical conditions, including liver or kidney disease.

Children and adolescents

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

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Prezel and certain other medicines may influence each other (interaction). When taken with certain other medicines, *Prezel* 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 *Prezel* is taken together with medicines containing:

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

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Alcohol

Prezel may be taken with oral contraceptives. Prezel with food, drink and alcohol. Prezel capsules may be taken with or without food. It is advised not to drink alcohol while taking Prezel.

How to use Prezel

- How much & when to use it

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will determine what dose is appropriate for you.

Prezel is for oral use only. Peripheral and central neuropathic pain, fibromyalgia, epilepsy or Generalised 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 Prezel either twice or three times a day. For twice a day take Prezel once in the morning and once in the evening, at about the same time each day. For three times a day take Prezel 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 Prezel 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 Prezel 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.

- How long to use it

Continue taking Prezel until your doctor tells you to stop.

- If you forget to use it

It is important to take your Prezel 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 use too much (overdose)

Call your doctor or go to the nearest hospital emergency unit immediately.

Take your box of Prezel capsules with you. You may feel sleepy, confused, agitated, or restless as a result of taking more Prezel than you should. Fits have also been reported.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Prezel.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking Prezel unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of 1 week.

After stopping long and short-term Prezel treatment, you need to know that you may experience certain side effects. These include, trouble sleeping, headache, nausea, feeling anxious, diarrhoea, flu-like symptoms, convulsions, nervousness, depression, pain, sweating, and dizziness. These symptoms may occur more commonly or severely if you have been taking Prezel for a longer period of time.

Do not take any new medicines without consulting your doctor. Do not drink alcohol while taking Prezel.

Do not give Prezel to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Prezel 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.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

If you have diabetes, you should pay attention to your skin while taking Prezel 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 Prezel. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 Prezel

- Storage

Keep this medicine out of the sight and reach of children. Do not store above 30 °C. Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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PREZEL 150 (PREGABALIN CAPSULES 150MG)

Pregabalin Capsules 75mg/150mg

Product Description

- What it looks like

75 mg capsules:

Size '4' hard gelatin capsules, reddish brown cap with creamish colour body.

150 mg capsules:

Size '2' hard gelatin capsules, creamish cap with creamish colour body.

Blisters packs: Blister pack of 10 capsules. Such 3 blisters of 10 Capsules each are packed in a carton along with insert.

- Ingredients

Active ingredient:

The active substance is pregabalin. Each capsule contains 75 mg or 150 mg pregabalin.

Inactive ingredients:

The other ingredients are pregelatinised starch, purified talc in capsule contents.

The other ingredients of 75 mg capsules are titanium dioxide, gelatin, iron oxide red, sodium lauryl sulphate & purified water

The other ingredients of 150 mg capsules are titanium dioxide, gelatin, sodium lauryl sulphate & purified water

- MAL numbers:

Prezel 75 mg capsules:

MAL20096013AZ

Prezel 150 mg capsules:

MAL20096014AZ

Manufacturer

Ind-Swift Laboratories Limited, Off-NH-21, Village Jawaharpur, Tehsil Derabassi, Distt. S.A.S Nagar, (Mohali) Punjab (India) Pin -140507

Product Registration Holder Synerrv

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