

Package leaflet: Information for the patient

Prebaxo 50 mg

Prebaxo 75 mg

Prebaxo 150 mg

Pregabalin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms and signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. **What Prebaxo is and what it is used for**
2. **What you need to know before you take Prebaxo**
3. **How to take Prebaxo**
4. **Possible side effects**
5. **How to store Prebaxo**
6. **Contents of the pack and other information**

1. What Prebaxo is and what it is used for

Prebaxo is a prescription medicine used in adults and older to treat:

- pain from damaged nerves (neuropathic pain) that happens with diabetes
- pain from damaged nerves (neuropathic pain) that follows healing of shingles
- fibromyalgia (pain all over your body)
- pain from damaged nerves (neuropathic pain) that follows spinal cord injury

It is not known if Prebaxo is safe and effective in people under 17 years of age for the treatment of fibromyalgia and neuropathic pain with diabetes, shingles, or spinal cord injury.

2. What you need to know before you take Prebaxo

Do not take Prebaxo:

If you are allergic to pregabalin or any of the other ingredient of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Prebaxo if you:

- have or have had depression, mood problems or suicidal thoughts or behavior.
- have breathing problems.
- 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, street drugs, or alcohol in the past.
- have ever had swelling of your face, mouth, tongue, lips, gums, neck, or throat (angioedema).

Other medicines and Prebaxe

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines or any medicines obtained without a prescription.

- 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 Prebaxe.
- Rosiglitazone or 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 Prebaxe.
- Any opioid pain medicine (such as oxycodone), or medicines for anxiety (such as lorazepam) or insomnia (such as zolpidem). You may have a higher chance for dizziness, sleepiness or serious breathing problems if these medicines are taken with Prebaxe.
- any medicines that make you sleepy.

Children and adolescents

The safety efficacy in children and adolescents (under 17 years of age) has not been established and therefore, Prebaxe should not be used in this age group.

Pregnancy, breastfeeding and fertility

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

Driving and using machines

Prebaxe may produce dizziness, sleepiness and decrease 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.

3. How to take Prebaxe

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

If you take more Prebaxe than you should

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

If you forgot to take Prebaxe

It is important to take your Prebaxe regularly at the same time each day. If you forgot to take dose, take it as soon as you remember unless it is time for your next dose.

If you stop taking Prebaxe

Do not stop taking Prebaxe unless your doctor tell you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you experience any of the following side effects stop using the medicine and seek medical help immediately:

- allergic reactions including swelling of your face, mouth, lips, gums, tongue, throat or neck, trouble breathing, rash, hives (raised bumps) or blisters.
- suicidal thoughts or actions
- dizziness and sleepiness
- breathing problems

Other side effects are listed below:

The most common side effects of Prebaxe in adults are:

- dizziness
- weight gain
- trouble concentrating
- blurry vision
- sleepiness
- swelling of hands and feet
- dry mouth

Prebaxe may cause following side effect, including:

- Muscle problems, muscle pain, soreness, or weakness. If you have these symptoms, especially if you feel sick and have a fever, tell your healthcare provider right away.
- Problems with your eyesight, including blurry vision. Call your healthcare provider if you have any changes in your eyesight.
- Weight gain. If you have diabetes, weight gain may affect the management of your diabetes. Weight gain can also be a serious problem.
- Feeling “high”.

Reporting of 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 can also report side effects directly via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prebaxe

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last day of that month.
- Do not Store above 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prebaxe contains

- The active substance is pregabalin. Each hard capsule contains either 50 mg, 75 mg or 150 mg of pregabalin.
- The other ingredients are starch and talc.
 - Capsule shell: gelatin, purified water, sodium lauryl sulfate and titanium dioxide (for 50 mg and 150 mg strengths) and FD &C Blue 1, FD&C: Red 40, FD& C Yellow 6, gelatin, purified water, sodium lauryl sulfate and titanium dioxide (for 75 mg strength).
 - Imprinting ink contains black iron oxide, potassium hydroxide, propylene glycol, purified water and shellac (for 50 mg, 75 mg and 150 mg strengths).

What Prebaxe looks like and content of the pack

Prebaxe 50 mg hard capsules

White to off white powder filled in size '3' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 50mg' on the cap and '678' on the body.

Prebaxe 75 mg hard capsules

White to off white powder filled in size '4' hard gelatin orange opaque and white opaque capsule linear printed in black ink with 'Cipla 75 mg' on the cap and '679' on the body.

Prebaxe 150 mg hard capsules

White to off white powder filled in size '2' hard gelatin white opaque and white opaque capsule linear printed in black ink with 'Cipla 150 mg' on the cap and '682' on the body.

Aluminium blister with PVC/PE/PVDC film (clear PVC film with PE, PVDC film)

Carton containing 3 blisters of 10 capsules.

Marketing Authorisation Holder and Manufacturer

Cipla Ltd.