

Package leaflet: Information for the patient

Prasolan 10 mg, 20 mg - Enteric-Coated Tablets

Rabeprazole sodium

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 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.

What is in this leaflet

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

1. What Prasolan is and what it is used for

Prasolan tablet contains the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

Prasolan tablets are used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus).
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called 'Helicobacter pylori' (H. Pylori), you will also be given antibiotics. Using Prasolan tablets and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back.

- Zollinger-Ellison Syndrome where your stomach produces too much acid.

2. What you need to know before you take Prasolan

Do not take Prasolan if:

- You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of Prasolan (listed in Section 6).
- You are pregnant or think that you are pregnant.
- You are breast-feeding.

Do not use Prasolan if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Prasolan.

Also see pregnancy and breast-feeding section.

Warnings and precautions

Consult your doctor or pharmacist before taking this medicine.

Take special care with Prasolan if:

- You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'.
- Blood and liver problems have been seen in some patients but often get better when Prasolan is stopped.
- You have a stomach tumour.
- You have ever had liver problems.
- You are taking atazanavir for HIV infection.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium.

As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.

- If you have ever had a skin reaction after treatment with a medicine similar to Prasolan that reduces stomach acid.
- If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Prasolan. Remember to also mention any other ill-effects like pain in your joints.

- You are due to have a specific blood test (Chromogranin A).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Prasolan.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Prasolan and see a doctor straight away.

Taking a proton pump inhibitor like Prasolan, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Children

This medicine should not be used in children.

Other medicines and Prasolan

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole or Itraconazole -used to treat infections caused by a fungus. Prasolan may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir- used to treat HIV-infection. Prasolan may lower the amount of this type of medicine in your blood and they should not be used together.
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor may temporarily stop your Prasolan treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Prasolan.

Pregnancy and breast-feeding

- Do not use Prasolan if you are pregnant or think you may be pregnant.
 - Do not use Prasolan if you are breast-feeding or planning to breast-feed.
- Consult your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

You may feel sleepy while taking Prasolan. If this happens, do not drive or use any tools or machines.

3. How to take Prasolan

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

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

Adult and elderly

For 'gastro-oesophageal reflux disease' (GORD)

Treatment of moderate to severe symptoms (symptomatic GORD)

- The usual dose is one Prasolan 10 mg tablet once a day for up to 4 weeks.
- Take the tablet in the morning before eating.
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one Prasolan 10 mg tablet as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The usual dose is one Prasolan 20 mg tablet once a day for 4 to 8 weeks.
- Take the tablet in the morning before eating.

Long-term treatment of symptoms (GORD maintenance)

- The usual dose is one Prasolan 10 mg or 20 mg tablet once a day for as long as your doctor has told you.
- Take the tablet in the morning before eating.
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

For ulcers of the stomach (peptic ulcers)

- The usual dose is one Prasolan 20 mg tablet once a day for 6 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Prasolan for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)

- The usual dose is one Prasolan 20 mg tablet once a day for 4 weeks .
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Prasolan for another 4 weeks if your condition does not improve.

For ulcers caused by H. Pylori infection and to stop them coming back

- The usual dose is one Prasolan 20 mg tablet twice a day for seven days.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.
- For further information on the other medicines used for the H. Pylori treatment, see the individual product information leaflets.

Zollinger-Ellison Syndrome where excess acid is produced in the stomach

- The usual dose is three Prasolan 20 mg tablets once a day to start with.
- The dose may then be adjusted by your doctor depending on how you respond to the treatment.
- If you are on long-term treatment you will need to see your doctor at regular intervals for review of your symptoms and dose.

Children

This medicine should not be used in children.

Patients with liver problems

Caution should be applied for patients with liver problems.You should consult your doctor before starting and during treatment with Prasolan.

If you take more Prasolan than you should

If you take more Prasolan than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Prasolan

- If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next tablet at the usual time. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.
- If you forget to take your medicine for more than 5 days, consult your doctor before taking any more medicine.

If you stop taking Prasolan

Relief of symptoms will normally occur before the ulcer has completely healed. It is important that you do not stop taking the tablets until told to do so by your doctor.

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

4. Possible side effects

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

The side effects are usually mild and improve without having to stop taking this medicine.

Some side effects can be serious and need immediate medical attention.

If you experience the following, stop taking Prasolan tablets and tell your doctor immediately or go to your nearest hospital:

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse.
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat.
- Bruising or bleeding easily. (These side effects are rare and affect less than 1 in 1,000 people).
- Severe skin blistering, or soreness or ulcers in your mouth and throat. (These side effects are very rare and affect less than 1 in 10,000 people).

Other possible side effects:

Common (affect less than 1 in 10 people)

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness or flu-like symptoms.
- Benign polyps in the stomach.

Uncommon (affect less than 1 in 100 people)

- Feeling nervous or drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Skin rash or redness
- Muscle, leg or joint pain
- Fractures of the hip, wrist and spine
- Bladder infection (urinary tract infection)
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests).

Rare (affect less than 1 in 1,000 people)

- Loss of appetite (Anorexia)
- Depression
- Hypersensitivity (includes allergic reactions)
- Visual disturbance
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites of your eyes (jaundice)
- Itchy rash or blistering skin
- Sweating
- Kidney problems
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Unknown frequency

- Breast swelling in men
- Fluid retention
- Inflammation of the gut (leading to diarrhoea)
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease).
- Rash, possibly with pain in the joints

If you are on Prasolan for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please consult your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Do not be concerned by this list of side effects. You may not get any of them.

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prasolan

- Keep this medicine out of the sight and reach of children.
- Do not use Prasolan after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not store above 30°C. keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. 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 Prasolan contains

- The active substance in Prasolan is rabeprazole sodium
 - Prasolan 10 mg: Each tablet contains 10 mg rabeprazole sodium
 - Prasolan 20 mg: Each tablet contains 20 mg rabeprazole sodium
- Tablet core: mannitol, magnesium oxide, low-substituted hypromellose, hypromellose, magnesium stearate
Tablet coating: ethylcellulose, hypromellose phthalate, acetylated monoglycerides, hypromellose, titanium dioxide, polyethylene glycol, red iron oxide (E172).

What Prasolan looks like and contents of the pack

- Prasolan tablets are pink, round, coated tablets.
- Prasolan 10 mg is available in boxes containing 28 tablets.
- Prasolan 20 mg is available in boxes containing 14 tablets.

Marketing Authorisation Holder and Manufacturer

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Registration No for Prasolan 10 mg in Lebanon: 973028/01
Registration No for Prasolan 20 mg in Lebanon: 973029/01

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 pharmacist who sold the medicament.
- The doctor and the pharmacist 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.