Package leaflet: Information for the patient

Prucalopride 1 mg film-coated tablets
Prucalopride succinate

Is this leaflet hard to see or read? Phone 0800 198 5000 for help.

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. See section 4.

What is in this leaflet

1. What Prucalopride is and what it is used for

Prucalopride contains the active substance prucalopride.

Prucalopride belongs to a group of gut motility enhancing medicines (gastrointestinal prokinetics). It acts on the muscle wall of the gut, helping to restore the normal functioning of the bowel. Prucalopride is used for the treatment of chronic constipation in adults in whom laxatives do not work well enough.

Not for use in children and adolescents younger than 18 years.

2. What you need to know before you take Prucalopride

Do not take Prucalopride
- if you are allergic to prucalopride or any of the other ingredients of this medicine (listed in section 6),
- if you are on renal dialysis,
- if you suffer from perforation or obstruction of the gut wall, severe inflammation of the intestinal tract, such as Crohn's disease, ulcerative colitis or toxic megacolon/megarectum.

Warnings and precautions
Talk to your doctor before taking Prucalopride.

Take special care with Prucalopride and tell your doctor if you:

- suffer from severe kidney disease,
- suffer from severe liver disease,
- are currently under supervision by a doctor for a serious medical problem such as lung or heart

disease, nervous system or mental health problems, cancer, AIDS or a hormonal disorder.

If you have very bad diarrhoea, the contraceptive pill may not work properly and the use of an extra method of contraception is recommended. See the instructions in the patient leaflet of the contraceptive pill you are taking.

Prucalopride film-coated tablets contain Isomalt (E 953):
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

Prucalopride with food and drink
Prucalopride can be taken with or without food and drinks, at any time of the day.

Pregnancy and breast-feeding
Prucalopride is not recommended for use during pregnancy.

- Tell your doctor if you are pregnant or planning to become pregnant.
- Use a reliable method of contraception while you're taking Prucalopride, to prevent pregnancy.
- If you do become pregnant during treatment with Prucalopride, tell your doctor.

When breastfeeding, prucalopride can pass into breast milk. Breastfeeding is not recommended during treatment with Prucalopride. Talk to your doctor about this.

Ask your doctor for advice before taking any medicine.

Driving and using machines
Prucalopride is unlikely to affect your ability to drive or use machines. However, sometimes Prucalopride may cause dizziness and tiredness, especially on the first day of treatment, and this may have an effect on driving and use of machines.

3. How to take Prucalopride

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Take Prucalopride every day for as long as your doctor prescribes it.

The doctor may want to reassess your condition and the benefit of continued treatment after the first 4 weeks and thereafter at regular intervals.

The usual dose of Prucalopride for most patients is one 2 mg tablet once a day.

If you are older than 65 years or have severe liver disease, the starting dose is one 1 mg tablet once a day, which your doctor may increase to 2 mg once a day if needed.

Your doctor may also recommend a lower dose of one 1 mg tablet daily if you have severe kidney disease.

Taking a higher dose than recommended will not make the product work better.

Use in children and adolescents
Prucalopride is only for adults and should not be taken by children and adolescents up to 18 years.

If you take more Prucalopride than you should
It is important to keep to the dose as prescribed by your doctor. If you have taken more Prucalopride than you should, it is possible that you will get diarrhoea, headache and/or nausea. In case of diarrhoea, make sure that you drink enough water.

If you forget to take Prucalopride
Do not take a double dose to make up for a forgotten tablet. Just take your next dose at the usual time.

If you stop taking Prucalopride
If you stop taking Prucalopride your constipation symptoms may come back again.

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. The side effects mostly occur at the start of treatment and usually disappear within a few days with continued treatment.

The following side effects have been reported:
Very common: may affect more than 1 in 10 people
- headache,
- feeling sick,
- diarrhoea,
- abdominal pain.

Common: may affect up to 1 in 10 people
- decreased appetite,
- dizziness,
- vomiting,
- disturbed digestion (dyspepsia),
- windiness,
- abnormal bowel sounds,
- tiredness.

Uncommon: may affect up to 1 in 100 people
- tremors,
- pounding heart,
- rectal bleeding,
- increase in frequency of passing urine (pollakiuria),
- fever and feeling unwell.

If pounding heart occurs, please tell your doctor.

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Prucalopride

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 and carton after EXP. The expiry date refers to the last day of that month.

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 Prucalopride contains

The active substance is prucalopride.

One film-coated tablet of Prucalopride contains prucalopride succinate equivalent to 1 mg prucalopride.

The other ingredients are:

Tablet core
Microcrystalline cellulose (E 460 i); Isomalt (E 953); Sodium starch glycolate; Silica, colloidal anhydrous (E 551); Magnesium stearate (E 470 b)

Tablet coating
Hypromellose (E 464); Titanium dioxide (E 171); Macrogol; Talc (E 533 b)

What Prucalopride looks like and contents of the pack

Prucalopride 1 mg film-coated tablets are white coloured, round, biconvex film-coated tablets debossed with 'PRC' on one side and '1' on the other side. The average diameter of the tablets is 6.0 mm.

Prucalopride is available in packs of 7, 14, 28 or 84 film-coated tablets in aluminium/aluminium blister.

Prucalopride is available in packs of 7, 14, 28 or 84 film-coated tablets in clear- or opaque-PVC/PE/PVdC - aluminium blister.

Not all pack sizes may be marketed in your country.

Marketing authorisation holder and Manufacturer

Marketing authorisation holder
axunio Pharma GmbH
Van-der-Smissen-Straße 1
22767 Hamburg
Germany

Manufacturer
Delorbis Pharmaceuticals Ltd.
17 Athinon Str., Ergates Industrial Area
2643 Ergates,Lefkosia
Cyprus

This medicinal product is authorized in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Germany:	Prucaloprid axunio 1 mg Filmtabletten Prucaloprid axunio 2 mg Filmtabletten
Denmark:	Prucalopride axunio 1 mg filmovertrukne tabletter Prucalopride axunio 2 mg filmovertrukne tabletter
Schweden:	Prucalopride axunio 1 mg filmdragerade tabletter Prucalopride axunio 2 mg filmdragerade tabletter
United Kingdom:	Prucalopride 1 mg film-coated tablets Prucalopride 2 mg filmcoated tablets

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