Package leaflet: Information for the user

Prucalopride 1 mg film-coated tablets
Prucalopride 2 mg film-coated tablets

prucalopride

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 film-coated tablets are and what they are used for

Prucalopride film-coated tablets contain the active substance prucalopride.

Prucalopride film-coated tablets belong 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 film-coated tablets are 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 film-coated tablets

Do not take Prucalopride film-coated tablets:

- 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 or pharmacist before taking Prucalopride film coated tablets.

Take special care with Prucalopride film-coated tablets 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.

Other medicines and Prucalopride film-coated tablets

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

Prucalopride film-coated tablets with food and drink

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

Pregnancy, breast-feeding and fertility

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.

Prucalopride film-coated tablets are 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 film-coated tablets, to prevent pregnancy.
- If you do become pregnant during treatment with Prucalopride film-coated tablets, tell your doctor.

When breast-feeding, prucalopride can pass into breast milk. Breast-feeding is not recommended during treatment with Prucalopride film-coated tablets. Talk to your doctor about this.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Prucalopride film-coated tablets are unlikely to affect your ability to drive or use machines. However, sometimes Prucalopride film-coated tablets may cause dizziness and tiredness, especially on the first day of treatment, and this may have an effect on driving and use of machines.

Prucalopride film-coated tablets contain Lactose

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

3. How to take Prucalopride film-coated tablets

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 Prucalopride film-coated tablets every day for as long as your doctor prescribes them.

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 film-coated tablets 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.

Prucalopride film-coated tablets are only for adults and should not be taken by children and adolescents up to 18 years.

If you take more Prucalopride film-coated tablets than you should

It is important to keep to the dose as prescribed by your doctor. If you have taken more Prucalopride film-coated tablets 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 film-coated tablets

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 film-coated tablets

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 commonly (may affect more than 1 in 10 people): headache, feeling sick, diarrhoea and abdominal pain.

The following side effects have been reported commonly (may affect up to 1 in 10 people): decreased appetite, dizziness, vomiting, disturbed digestion (dyspepsia), windiness, abnormal bowel sounds, tiredness.

The following uncommon side effects have also been seen (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 film-coated tablets

This medicinal product does not require any special storage conditions.

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 carton and blister 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 film-coated tablets contain

The active substance is prucalopride.

Each 1 mg film-coated tablet contains 1 mg prucalopride (as succinate).

Each 2 mg film-coated tablet contains 2 mg prucalopride (as succinate).

- The other ingredients are

Tablet core:

Microcrystalline cellulose, colloidal silicon dioxide, lactose monohydrate (see section 2), magnesium stearate

Tablet coating:

1 mg: Hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol, triacetin

2 mg: Hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol, triacetin, iron oxide red (E172), iron oxide yellow (E172), indigo carmine aluminium lake (E132)

What Prucalopride film-coated tablets look like and contents of the pack

Prucalopride 1 mg film-coated tablets

White to off-white, 8.2 ± 0.5 mm diameter, round film-coated tablets debossed with ‘S30’ on one side and plain on the other side.

Prucalopride 2 mg film-coated tablets

Pink, 8.6 ± 0.5 mm diameter, round film-coated tablets debossed with ‘S31’ on one side and plain on the other side.

Prucalopride film-coated tablets are available in aluminium/aluminium perforated unit dose blisters (calendar marked) containing 7 tablets. Each pack contains 7 x 1, 14 x 1, 28 x 1 or 84 x 1 film-coated tablet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited
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Manufacturer

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Other sources of information

For information on large print, Braille or audio CD call emc accessibility on 0800 198 5000

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