Package leaflet: Information for the user

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

Read all of this leaflet carefully before you start taking this medicine because it contains importantinformation 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 effectsnot listed in this leaflet. See section 4.

What is in this leaflet

1. What Prucalopride Holsten is and what it is used for

Prucalopride Holsten contains the active substance prucalopride.

Prucalopride Holsten 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. Prucaloprideis 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 Holsten

Do not take Prucalopride Holsten:
- 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 Holsten.

Take special care with Prucalopride Holsten 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 methodof contraception is recommended. See the instructions in the patient leaflet of the contraceptive pill you are taking.

Other medicines and Prucalopride Holsten

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

Prucalopride Holsten with food and drink

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

Pregnancy and breast-feeding

Prucalopride Holsten 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 Holsten, to prevent pregnancy.
- If you do become pregnant during treatment with Prucalopride Holsten, tell your doctor.

When breast-feeding, prucalopride can pass into breast milk. Breast-feeding is not recommended duringtreatment with Prucalopride Holsten. Talk to your doctor about this.

Ask your doctor for advice before taking any medicine.

Driving and using machines

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

Prucalopride Holsten contains lactose

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

3. How to take Prucalopride Holsten

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Check withyour doctor or pharmacist if you are not sure. Take Prucalopride Holsten 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 Holsten 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 Holsten is only for adults and should not be taken by children and adolescents up to 18 years.

If you take more Prucalopride Holsten than you should

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

Holsten 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 Holsten
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 Holsten.

If you stop taking Prucalopride Holsten, 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 effectsmostly 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prucalopride Holsten

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.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throwaway medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Prucalopride Holsten contains
The active substance is prucalopride.
One film-coated tablet of Prucalopride Holsten 1 mg contains 1 mg prucalopride (as succinate). One film-coated tablet of Prucalopride Holsten 2 mg contains 2 mg prucalopride (as succinate).

The other ingredients are:

lactose monohydrate (see section 2), microcrystalline cellulose (E 460), silica colloidal anhydrous (E 551), magnesium stearate, hypromellose (E 464), titanium dioxide (E 171), macrogol (E 1521) and triacetin. The 2 mg tablet also contains iron oxide red (E 172), Indigo carmine aluminium lake (E 132) and iron oxide yellow (E 172).

What Prucalopride Holsten looks like and contents of the pack
Prucalopride Holsten 1 mg film-coated tablets are white to off- white, round biconvex, film-coated tablets debossed with “P1” on one side and no debossing on the other side. Thickness of tablets is 4 mm and diameter is 8 mm.
Prucalopride Holsten 2 mg film-coated tablets are pink, round biconvex, film-coated tablets debossed with “P2” on one side and no debossing on the other side. Thickness of tablets is 4 mm and diameter is 9 mm.

Prucalopride Holsten is provided in aluminium/aluminium blisters in cartons containing 14, 28 or 84 film-coated tablets (calendar package).

Not all pack sizes may be marketed in your country.

Marketing authorisation holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

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