Package leaflet: Information for the patient

Stercore1 mg filmomhulde tabletten
Stercore 2 mg filmomhulde tabletten
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 [Nationally completed name] is and what it is used for

Stercore 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.

Stercore 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 Stercore

Do not take Stercore
- 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 Stercore
- if you suffer from severe kidney disease.
- if you suffer from severe liver disease.
- if you 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 Stercore
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Stercorewith food and drink
Stercorecan 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.

Stercoreis 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 takingStercore, to prevent pregnancy. If you do become pregnant during treatment with Stercoretell your doctor.
When breast-feeding, prucalopride can pass into breast milk. Breast-feeding is not recommended during treatment with StercoreTalk to your doctor about this.

Driving and using machines
Stercoreis 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.

Stercorecontains lactose.
Each tablet of 1 mg contains 78.02 mg lactose monohydrate.
Each tablet of 2 mg contains 156.012 mg lactose monohydrate.
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 Stercore

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

Take Stercoreevery 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 recommended dose of Stercorefor 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
Stercoreis only for adults and should not be taken by children and adolescents up to 18 years.

If you take more Stercorethan you should
It is important to keep to the dose as prescribed by your doctor. If you have taken more Stercore 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 Stercore

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking Stercore
If you stop taking Stercore 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 national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stercore

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

This medicinal product does not require any special storage conditions.

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 Stercore contains
- The active substance is prucalopride. Each film coated tablet contains either 1 mg or 2 mg prucalopride (as succinate).
- The other ingredients are: *Tablet core*: cellulose, microcrystalline; lactose monohydrate; silica, colloidal anhydrous; magnesium stearate; *Film-coating*: hypromellose, lactose monohydrate, titanium dioxide, triacetin; red iron oxide (*2 mg tablet*).

What Stercore looks like and contents of the pack
1 mg: White, round, bioconvex, film-coated tablets embossed ‘10’ on one side, plain on the other side, with diameter of nucleus 6 mm.

2 mg: Pink, round, bioconvex, film-coated tablets embossed ‘20’ on one side, plain on the other side, with diameter of nucleus 8 mm.

Stercore1 mg and 2 mg film-coated tablets are packed in Alu/Alu blisters.
Packs of 7, 14, 28 or 84 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Medochemie Ltd
1 – 10 Constantinoupoleos Str, Limassol 3505, Cyprus

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