

Package leaflet: Information for the user

Xyloproct rectal ointment Xyloproct suppositories lidocaine, hydrocortisone acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without a prescription. Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Contact your doctor if the symptoms worsen or do not improve within 2–3 weeks.

What is in this leaflet:

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

1. What Xyloproct is and what it is used for

Xyloproct rectal ointment and suppositories contain two active ingredients (lidocaine and hydrocortisone) which work in different ways.

Hydrocortisone relieves the swelling. Lidocaine relieves pain and itching.

Xyloproct is used to treat haemorrhoids and superficial irritation of the rectum in adults.

2. What you need to know before you use Xyloproct

Do not use Xyloproct

- if you are allergic to lidocaine, hydrocortisone or any of the other ingredients in Xyloproct (listed in section 6).

Warnings and precautions

- Haemorrhoids often recur due to underlying constipation issues.
- Follow the recommended dosage carefully as higher doses can lead to more side effects.
- You should contact your doctor if there has been no improvement after 2–3 weeks of treatment with Xyloproct.
- If the skin around the rectal opening becomes irritated or starts to bleed you should stop the treatment and contact your doctor.
- Avoid contact with the eyes. Wash hands thoroughly after use.
- If you have porphyria (hereditary metabolism disorder) you should contact your doctor before you start treatment with Xyloproct.

Other medicines and Xyloproct

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

Xyloproct can affect or be affected by certain medicines that contain the following active substances:

- other local anaesthetics
- medicines for irregular heart activity (so-called antiarrhythmics).

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

No adverse effects on the foetus have been shown. However, the lowest possible dose and shortest possible treatment time should be sought when using Xyloproct during pregnancy.

Breast-feeding

The active substances in Xyloproct are excreted into human milk, but are unlikely to affect a breastfed child. However, consult your doctor in cases of more than temporary use of Xyloproct during breast-feeding.

Driving and using machines

When used at recommended doses, Xyloproct will not affect your ability to drive a car or use machines.

Xyloproct contains cetyl alcohol and stearyl alcohol

Xyloproct rectal ointment contains cetyl alcohol and stearyl alcohol, which can cause local skin reactions (e.g. contact dermatitis).

3. How to use Xyloproct

Always use Xyloproct as directed by your doctor. Follow the recommended dosage carefully as higher doses can lead to more side effects. Check with your doctor or pharmacist if you are not sure.

Usual dose

Rectal ointment: Apply in and around the rectal opening once or several times daily. You can also use the rectal ointment for painful bowel motions. Up to 6 g of rectal ointment can be applied per 24 hours. The rectal ointment is easily washed off with water. Perforate the protective membrane on the tube by pushing down on it with the protective cap.

Suppositories: Insert one suppository into the outer part of the rectal opening morning and evening as well as when required following each bowel movement. The suppository is to be inserted with the blunt end first.

It is important that the suppository remain in place until it has melted. Up to 5 suppositories can be used per 24 hours.

The treatment period should not exceed 3 weeks.

If you use more Xyloproct than you should

If you have taken too much medicine or if a child, for example, has taken the medicine by accident, you should contact a doctor or hospital to get an opinion of the risk and advice on action to be taken.

4. Possible side effects

Like all medicines, Xyloproct can cause side effects, although not all users experience them. The risk of side effects increases with a longer duration of treatment.

Uncommon (affects less than 1 in 100 users): Skin inflammation due to hypersensitivity.

Rare (affects less than 1 in 1,000 users): Allergic reactions; in the most severe cases: anaphylactic shock (severe allergic reaction with e.g. skin rash, swelling, fever, difficulty breathing and fainting). If you experience severe allergic reactions such as this you should immediately seek help at a hospital Emergency Department.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Xyloproct

Rectal ointment: Store in a refrigerator (2°C – 8°C). The rectal ointment can be stored at a maximum of 25°C for 2 months.

Suppositories: Store in a refrigerator (2°C – 8°C). Do not freeze. The suppositories can be stored at a maximum of 25°C for 2 months.

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 'Utg.dat.'. 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 Xyloproct contains

Rectal ointment:

- The active substances are lidocaine 50 mg and hydrocortisone acetate 2.5 mg.
- The other ingredients are aluminium diacetate, zinc oxide, cetyl alcohol, stearyl alcohol, macrogol and water.

Suppository:

- The active substances are lidocaine 60 mg and hydrocortisone acetate 5 mg.
- The other ingredients are aluminium diacetate, zinc oxide and hard fat.

What Xyloproct looks like and contents of the pack

Rectal ointment:

White to pale yellow homogenous ointment.

Pack size: Tube containing 20 g.

Suppositories:

White or pale yellow suppositories.

Pack sizes: Carton containing 10 and 50 (on prescription only) suppositories, respectively.

Marketing Authorisation Holder:

Aspen Pharma Trading Limited
3016 Lake Drive, Citywest Business Campus
Dublin 24, Ireland
Tel.: 0046 856642572

Manufacturer (rectal ointment):

AstraZeneca AB, Södertälje, Sweden
or
Recipharm Karlskoga AB, Karlskoga, Sweden
Or
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

Manufacturer (suppositories):

AstraZeneca AB, Södertälje, Sweden
or
Recipharm Karlskoga AB, Karlskoga, Sweden

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