

PACKAGE LEAFLET: INFORMATION FOR THE USER

Xyloproct® 5%/0.275% Ointment lidocaine, hydrocortisone acetate

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

In this leaflet:

1. What Xyloproct Ointment is and what it is used for
2. Before you use Xyloproct Ointment
3. How to use Xyloproct Ointment
4. Possible side effects
5. How to store Xyloproct Ointment
6. Further information

1. What Xyloproct Ointment is and what it is used for

What Xyloproct Ointment is

The name of your medicine is 'Xyloproct 5%/0.275% Ointment'. It is referred to as 'Xyloproct Ointment' in the rest of this leaflet.

Xyloproct Ointment contains two medicines: lidocaine and hydrocortisone.

- Lidocaine (sometimes known as lignocaine) belongs to a group of medicines called local anaesthetics.
- Hydrocortisone belongs to a group of medicines called corticosteroids.

What Xyloproct Ointment is used for

Xyloproct Ointment may be used in adults and children of all ages for the following reasons:

- to relieve itching around the back passage (anus) or female private parts (genitals).
- to relieve the symptoms of piles (haemorrhoids) and other problems that affect the back passage. These symptoms include pain and inflammation.

2. Before you use Xyloproct Ointment

Do not use Xyloproct Ointment if:

- You are allergic (hypersensitive) to lidocaine or hydrocortisone or any of the other ingredients of Xyloproct Ointment (listed in Section 6: Further information).
- You have ever had an allergic reaction to other local anaesthetics or to other corticosteroid medicines.
- You have an infection where the ointment is going to be put and the infection is not being treated.
- You are not in hospital and you are taking medicines for an uneven heart beat (such as amiodarone or sotalol).

Do not use Xyloproct Ointment if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Xyloproct Ointment.

Take special care with Xyloproct Ointment

Check with your doctor or pharmacist before using Xyloproct Ointment if:

- Your skin is very thin or fragile where the ointment is going to be put.
- You have an infection where the ointment is going to be put. If this applies to you, your doctor may ask you to use another medicine as well as Xyloproct Ointment.
- You have ever been told that you have a rare disease of the blood pigment called 'porphyria' or anyone in your family has it.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Xyloproct Ointment can affect the way some medicines work and some medicines can have an effect on Xyloproct Ointment.

In particular, tell your doctor or pharmacist if you are taking or using any of the following medicines:

- Medicines for an uneven heart beat (such as amiodarone or sotalol).
- Other local anaesthetics.

Pregnancy and breast-feeding

Talk to your doctor before using Xyloproct Ointment if you are pregnant, may become pregnant or are breast-feeding. Your doctor will decide if you can use Xyloproct Ointment during this time.

3. How to use Xyloproct Ointment

Always use Xyloproct Ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Always wash your hands well before and after using this medicine.

How much Xyloproct Ointment to use

- Your doctor will tell you how much ointment to use and how often to use it.
- Usually the ointment should be put on the affected area several times a day.
- Up to 6 g (grams) of ointment can be used each day. This is about a third of a tube.

How long to use Xyloproct Ointment for

- Xyloproct Ointment should only be used for limited periods of time.
- With longer periods of treatment (up to 3 weeks) your doctor may suggest that you have a break from treatment, especially if you are getting irritation around or inside where the ointment is applied.
- If you get irritation, your doctor may do a patch test to see if it is being caused by Xyloproct Ointment.

Using the applicator

- The ointment comes with an applicator. Your doctor will tell you if you need to use this.
- If your doctor tells you to use the applicator, be careful not to put too much ointment inside the back passage, especially if it is being given to a child.
- Clean the applicator very well after each use.

If you use more Xyloproct Ointment than you should

- If you use too much ointment talk to your doctor as soon as possible.
- It is particularly important to talk to your doctor as soon as possible if a child has been given too much ointment. This is because fits have sometimes happened in children who have been given too much.

4. Possible side effects

Like all medicines, Xyloproct Ointment can cause side effects, although not everybody gets them.

Stop using Xyloproct Ointment and talk to your doctor straight away if you notice any of the following – you may need urgent medical treatment:

- Sudden onset of rash, itching or hives on the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

This may mean that you are having an allergic reaction.

Stop using Xyloproct Ointment and talk to your doctor if you notice any of the following:

- Soreness in your back passage.
- Bleeding from your back passage.

Other possible side effects:

- Redness, swelling and itching where Xyloproct Ointment has been put on your body.

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 at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xyloproct Ointment

- The ointment should be kept in a safe place where children cannot reach and see it.
- Xyloproct Ointment can be stored between 2°C and 8°C (in a refrigerator).
- When you start using the ointment, the tube can be stored at room temperature (up to 25°C) for up to 2 months. Any remaining ointment should then be discarded.
- Do not use Xyloproct Ointment after the expiry date which is stated on the tube.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Further information

What Xyloproct Ointment contains

The active substances in Xyloproct Ointment are lidocaine and hydrocortisone acetate. Each gram of Xyloproct Ointment contains 50 mg (milligrams) of lidocaine and 2.75 mg of hydrocortisone acetate.

The other ingredients are zinc oxide, aluminium acetate, stearyl alcohol, cetyl alcohol, purified water and macrogol (3350 and 400).

What Xyloproct Ointment looks like and contents of the pack

Xyloproct Ointment is white to slightly yellow in colour. It comes in an aluminium tube that contains 20 g (grams) of the ointment. An applicator is provided.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Xyloproct Ointment is held by AstraZeneca UK Limited, 600 Capability Green, Luton, LU1 3LU, UK.

Xyloproct Ointment is manufactured by AstraZeneca AB, S-151 85, Södertälje, Sweden.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Xyloproct Ointment**

Reference number **17901/0179**

This is a service provided by the Royal National Institute of Blind People.

Leaflet prepared: January 2014

© AstraZeneca 2014

Xyloproct is a trade mark of the AstraZeneca group of companies.

PAI 14 0007