

- **PATIENT
INFORMATION
LEAFLET**

**Ultraproct® 0.92 mg/g +
0.95mg/g + 5 mg/g Rectal
Ointment**
Fluocortolone pivalate
Fluocortolone caproate
Cinchocaine hydrochloride

**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 you experience any side effect and this becomes serious, tell your doctor or pharmacist.

In this leaflet:

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

1. **What Ultraproct is and what it is used for**

Ultraproct contains a substance which reduces inflammation (fluocortolone), and a local anaesthetic (cinchocaine) which relieves pain.

This medicine is used for the relief of the inflammation, swelling, itching and soreness of piles (haemorrhoids) and to relieve itching of the anus (back passage). Ultraproct is intended for short term treatment.

2. **Before you use Ultraproct**

Do not use Ultraproct if you:

- are allergic (hypersensitive) to fluocortolone pivalate, fluocortolone caproate, cinchocaine hydrochloride, other local anaesthetics or any of the other ingredients of Ultraproct.
- have a viral infection (e.g. herpes, shingles, chicken-pox)
- have any bacterial or fungal infections of the skin for which you are not receiving treatment

Take special care with Ultraproct

- Long-term continuous treatment should be avoided because it can cause the skin to thin and deteriorate in the affected area (see section 4. "Possible Side Effects") and some of the medicine may be absorbed into the blood stream. Ultraproct should not normally be used for longer than 1 week.
- If the area treated with Ultraproct is also infected your doctor should prescribe another medicine to use with Ultraproct, to treat the infection.
- Do not allow Ultraproct to come into contact with the eyes.
- In case latex products such as condoms are used concomitantly in the area of treatment with Ultraproct rectal ointment its ingredients may cause damage to those latex products. Therefore, these may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information.

If symptoms do not improve, consult the doctor again.

Contact your doctor if you experience blurred vision or other visual disturbances.

Taking other medicines

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Ultraproct and your doctor may wish to monitor you carefully if you are taking these medicines (including some

medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast feeding

Contact your doctor for advice before using this medicine if you are pregnant or intending to become pregnant or are breastfeeding and use it only as the doctor prescribes.

There may be a very small risk to the development of a baby in pregnant women treated with Ultraproct. As with most medicines, this risk is likely to be greatest during the first 3 months of pregnancy.

3. How to use Ultraproct

Always use Ultraproct exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not use Ultraproct for more than one week.

Always wash your hands before and after applying Ultraproct.

How to use Ultraproct Ointment:

1. Before you use the ointment, gently but thoroughly wash and dry the anus (back passage) and the skin around it.
2. If the ointment is to be used for the area **around** the anus:
 - squeeze a small quantity (about the size of a pea) on to the top of your finger.
 - spread it gently over the skin and just inside the anus.
 - do not rub it in.
3. If the ointment is to be used **inside** the anus:
 - put the separate applicator (nozzle) onto the tube.
 - squeeze the tube until the applicator is full of ointment.
 - insert the applicator very carefully into the anus until the whole length of the applicator is inside.
 - then, while squeezing the tube gently, withdraw the applicator.
 - wash the applicator carefully in hot soapy water and rinse thoroughly.
 - after each use, clean the applicator with a paper towel, remove the remaining product in the applicator with a cotton swab and clean it again with a paper towel. Rinse the applicator under warm water for about 1 minute

and dry the applicator with a paper towel. Do not use the applicator if damaged.

Generally, the ointment should be applied thinly twice a day, but it may be applied three or four times on the first day, to obtain quick relief.

If you use more Ultraproct than you should

If you accidentally swallow Ultraproct, contact your doctor or pharmacist.

If you forget to use Ultraproct

Do not use or take a double dose to make up for a forgotten dose. When you remember, use/take the next prescribed dose and continue with the treatment. See your doctor or pharmacist if you are worried.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ultraproct can cause side effects, though not everybody gets them.

Some thinning of the skin may occur if too much Ultraproct is applied for long periods of time.

Allergic skin reactions may occur in rare cases.

Blurred vision may occur, however the frequency is not known.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ultraproct

Keep out of the reach and sight of children.

Do not store above 25°C. Replace the cap tightly after use. Once opened, use within 3 months.

The expiry date is printed on the tube and on the pack after "EXP". The expiry date refers to the last day of that month. Do not use it after this date.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Ultraproct Ointment contains

The active substances are fluocortolone pivalate, fluocortolone caproate and cinchocaine hydrochloride.

1g of Ultraproct Ointment contains 0.92 mg fluocortolone pivalate, 0.95 mg fluocortolone caproate and 5 mg cinchocaine hydrochloride.

The other ingredients are:

2-octyldodecanol
Castor oil, refined
Castor oil, hydrogenated
Macrogol-400-monoricinoleate
Perfume oil citrus-rose

What Ultraproct looks like and contents of the pack

Ultraproct Ointment is a colourless to faintly yellow rectal ointment. It is supplied in tubes of 30 g.

The pack also contains a plastic applicator/nozzle.

Marketing Authorisation Holder

Bayer Limited
The Atrium
Blackthorn Road
Dublin 18

Manufacturer:

LEO Pharma Manufacturing Italy S.r.l.,
Segrate
Via E. Schering 21
20090 Segrate (Milano)
Italy

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