

## Package leaflet: Information for the user

### Ultraproct® 0.92 mg/g + 0.95 mg/g + 5 mg/g Rectal Ointment

**Fluocortolone pivalate**  
**Fluocortolone caproate**  
**Cinchocaine hydrochloride**

#### Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. **What Ultraproct® is and what it is used for**
2. **What you need to know before you use Ultraproct®**
3. **How to use Ultraproct®**
4. **Possible side effects**
5. **How to store Ultraproct®**
6. **Contents of the pack and other 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. What you need to know 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 (listed in section 6).
- 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.

#### Warnings and precautions. Talk to your doctor, pharmacist or nurse before using 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.

#### Other medicines and Ultraproct

- Tell your doctor or pharmacist 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 breast-feeding 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.

**This medicine contains castor oil, castor oil hydrogenated and macrogol 400 monoricinoleate that may cause skin reactions.**

**This medicine contains perfume oil, citrus-rose fragrance with amylcinnamal, amylcinnamylalcohol, benzyl alcohol, benzyl benzoate, cinnamal, cinnamic alcohol, citral, citronellol, coumarin, d-limonene, eugenol, farnesol, geraniol, hexyl cinnamaldehyde, hydroxycitronella, linalool. These allergens may cause allergic reactions.**

#### 3. How to use Ultraproct®

Always use this medicine exactly as your doctor or pharmacist has told you. 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, this medicine can cause side effects, although 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto: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 this medicine out of the sight and reach of children.

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

Do not store above 25°C. Replace the cap tightly after use.

Once opened, use within 3 months.

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 Ultraproct Ointment contains**

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

1 g 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  
(contains amylcinnamal,  
amylcinnamylalcohol, benzyl alcohol,  
benzyl benzoate, cinnamal, cinnamic  
alcohol, citral, citronellol, coumarin,  
d-limonene, eugenol, farnesol,  
geraniol, hexyl cinnamaldehyde,  
hydroxycitronella, linalool (See  
section 2).

#### **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**

Karo Pharma AB  
Box 16184  
103 24 Stockholm  
Sweden

#### **Manufacturer:**

LEO Pharma Manufacturing Italy S.r.l.  
Via E. Schering 21  
20054 Segrate  
Milano  
Italy

**This leaflet was last revised:  
October 2021**

**For information in  
large print, Braille or  
audio/CD, telephone  
+353 (0) 1 490 8924**

® Registered Trade Mark