



**Bayer HealthCare Manufacturing S.r.l. (Segrate)**

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PZ (technical drawing):	<b>2585A-4</b>	Item n°:	<b>REG</b>	Replaces: 82092803
Laetus-code n°: Bar-code n°:	<b>0013</b>	Client:	<b>044</b>	
Name:	<b>Ultraproct ointment</b>	Country:	<b>Great Britain (Meadow)</b>	
Colors:	<b>Black</b>	Format label:		
Approved.:		Date:		



MEADOW

**Patient information Leaflet**

**Ultraproct® Ointment  
Ultraproct® Suppositories**

(fluocortolone pivalate, fluocortolone hexanoate and 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please 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 fluocortolone which belongs to a group of medicines known as the corticosteroids which reduce inflammation and itching. Ultraproct also contains a substance

called cinchocaine hydrochloride which is a local anaesthetic to relieve pain. Ultraproct can be used for the short-term (5-7 days) relief of inflammation, swelling, itching and soreness of piles (haemorrhoids) and to relieve itching of the anus (back passage).

This leaflet covers the following products:

- Ultraproct Suppositories
- Ultraproct Ointment

In this leaflet they are jointly referred to as Ultraproct.

Your doctor will prescribe the correct product to treat your specific condition.

**2. Before you use Ultraproct**

**Do not use Ultraproct if you:**

- are **allergic** (hypersensitive) to local anaesthetics or any other ingredients of this medicine (see section 6)
- suffer from a **viral skin infection** such as cold sores, herpes, shingles or chickenpox
- have a **bacterial** or **fungal** infection for which you are not receiving treatment
- are **pregnant** or **breast-feeding**, unless recommended otherwise by your doctor

Tell your doctor if you believe any of the above conditions apply to you.

**Take special care with Ultraproct:**

Ultraproct **must not** come into contact with your eyes. Rinse with cold water if accidental contact occurs.

Avoid using Ultraproct for a long time because it increases the risk of side effects.

If the area treated with Ultraproct is also infected your doctor will prescribe another medicine to treat the infection.

*Infants and Children*

Ultraproct is not for use in infants and is not recommended for use in children under 12 years of age unless directed by a doctor.

*Using dressings over the treatment area*

Do not use waterproof dressings over the affected skin.

**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**

Even at the usual dose, the possibility of a very small risk to the development of a baby in pregnant women treated with Ultraproct cannot be entirely ruled out. **Therefore, this medicine should not be used if you are pregnant, trying to become pregnant or are breast-feeding unless considered essential by your doctor.**

**Driving and using machines**

Ultraproct does not impair your ability to drive or operate machinery.

**Important information about some of the ingredients of Ultraproct Ointment**

Ultraproct Ointment contains castor oil and hydrogenated castor oil, which may cause skin reactions.

**3. How to use Ultraproct**

Wash your hands before and after using Ultraproct.  
Do not use Ultraproct for more than 7 days.



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**Ointment:**

The ointment should be applied twice a day.

You can apply it three or four times a day during the first day of the treatment to obtain quick relief.

Before you use the ointment wash your anus and area around it gently but thoroughly.

*If the ointment is to be used for the area around the anus:*

- Squeeze a small amount (about the size of a pea) on the tip of your finger
- Spread it gently over the skin and just inside the anus
- Do not rub it in

*If the ointment is to be used inside the anus:*

- Attach the nozzle onto the tube
- Squeeze the tube until the nozzle is full of ointment
- Insert the nozzle carefully into the anus until the whole length of the nozzle is inside
- While squeezing the tube gently, slowly withdraw the nozzle
- Wash the nozzle in hot soapy water and rinse thoroughly

**Suppositories**

You should use one suppository per day, preferably after a bowel movement.

If your discomfort is severe you can insert two or three suppositories per day at the beginning of your treatment.

If the suppositories become too soft due to warm temperature, you can harden them by putting into cold water or into a fridge for a while.

- Find the small tear in the foil and remove the covering foil by tearing it in half
- Insert the whole suppository into the anus gently
- To make insertion easier you can stand with one foot raised on a chair or squat down.

**If accidentally swallowed**

If you or someone else accidentally swallows Ultraproct it is

unlikely to be harmful but contact your doctor or pharmacist if you are concerned.

**If you forget to use Ultraproct**

If you have forgotten to use your medicine, do not make up for it by using extra. When you remember, use the next prescribed dose and continue with your treatment schedule.

**If you use more Ultraproct than you should**

If you think you have used more Ultraproct than you should, or if you have used it for longer than 7 days, tell your doctor or pharmacist.

**4. Possible side effects**

Ultraproct can cause side effects although not everybody gets them.

Rarely an allergic reaction to Ultraproct may occur. If you feel you have experienced an allergic reaction, stop using this medicine and inform your doctor or pharmacist immediately.

Thinning of the skin may occur if Ultraproct is applied for long periods of time.

**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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Ultraproct****Keep out of the reach and sight of children.**

Do not use after the expiry date on the pack.

Suppositories: Store in a refrigerator.

Ointment: Do not store above 25° C.

**6. Further information****What Ultraproct contains:**

*One Ultraproct Suppository* contains the **active ingredients** 0.61mg fluocortolone pivalate, 0.63mg fluocortolone hexanoate and 1mg cinchocaine hydrochloride.

The other ingredient is hard fat.

*1g of Ultraproct Ointment* contains the **active ingredients** 0.92mg fluocortolone pivalate, 0.95mg fluocortolone hexanoate and 5mg cinchocaine hydrochloride.

The other ingredients are polyethylene glycol 400 monoricinoleate, castor oil, hydrogenated castor oil, 2-octyldodecanol, citrus rose perfume oil.

**What Ultraproct looks like and contents of the pack:**

Ultraproct Suppositories are yellowish white in colour and are available in packs of twelve.

Ultraproct Ointment is yellowish white in colour and available in 30 g tubes with an applicator.

**Marketing authorisation holder:**

Meadow Laboratories Limited  
Unit 13, Falcon Business Centre  
Ashton Road  
Romford  
Essex RM3 8UR  
United Kingdom

**Manufacturer:**

Bayer Healthcare Manufacturing S.r.l.  
Via E. Schering 21  
20090 Segrate (MI)  
Italy

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