ULTRAPROCT®

Ointment contains 0.92 mg fluocortolone pivalate, 0.95 mg fluocortolone hexanoate and 5 mg cinchocaine hydrochloride per 1 g of ULTRAPROCT®;
1 suppository contains 0.61 mg fluocortolone pivalate, 0.63 mg fluocortolone hexanoate and 1 mg cinchocaine hydrochloride.

What is in this leaflet

Please read this leaflet carefully before you start using ULTRAPROCT®. It will advise you about how to take ULTRAPROCT® properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

This preparation has been prescribed for you personally and you should not pass it on to others. It may harm them.

What is ULTRAPROCT® used for and how does it work

ULTRAPROCT® is used for patients suffering from haemorrhoids, superficial anal fissures and proctitis.

Before you use ULTRAPROCT®

Do not use ULTRAPROCT® if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use ULTRAPROCT®.

You must not use ULTRAPROCT® if:

- you are pregnant or think you might be pregnant. Corticosteroid preparations such as ULTRAPROCT® should not be applied during the first three months of pregnancy.
- you are allergic to any of the ingredients of ULTRAPROCT®.
- you suffer from Tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. vaccinia, chickenpox).

If any of these conditions appear for the first time while using ULTRAPROCT®, stop taking it at once and consult your doctor.
What else you should know

Prolonged use should be avoided (see the side effects section of this leaflet).

ULTRAPROCT® and breast-feeding

ULTRAPROCT® is generally not recommended for use during breast-feeding. If you wish to use ULTRAPROCT®, please seek the advice of your doctor.

ULTRAPROCT® and pregnancy

ULTRAPROCT® must not be used by women who are pregnant, or who think they may be pregnant.

If you suspect that you are pregnant while you are already using ULTRAPROCT®, you should consult your doctor as soon as possible.

How to use ULTRAPROCT® properly

The anal region should be cleaned thoroughly before using ULTRAPROCT®, which is best applied after defecation. There is usually a rapid improvement, but this should not mislead one into stopping treatment too soon. To avoid relapses, ULTRAPROCT® should be continued for at least one week, though less frequently (ointment once a day or one suppository every other day), even when the symptoms have completely disappeared. However, duration of treatment should, as far as possible, not exceed 4 weeks.

Ointment

Unless otherwise prescribed by the doctor, generally, apply twice daily, or on the first day for faster symptomatic relief, up to four times.

Smear a little ointment (about the size of a pea) around the anus and in the anal ring with a finger, using the fingertip to overcome the resistance of the sphincter. Before applying within the rectum, the enclosed nozzle should be screwed on to the tube. However, for very inflamed and hence painful lesions, it is advisable initially to apply the ointment internally with the finger.

Protruding lumps should be smeared thickly and pressed carefully back with the finger.

Suppositories

In general, insert one suppository daily high into the rectum. If symptoms are severe insert one suppository two to three times on the first day.

The consistency of suppositories that have become soft due to warmth should be restored by placing them in cold water before the covering is removed.
**Overdosage**

There has been no report of toxicity even after inadvertent overdose. However if ULTRAPROCT® is swallowed systemic side effects may result and may manifest as severe cardiovascular (ranging from depression to cessation of cardiac function) and CNS symptoms (convulsions; inhibition to arrest of respiratory function), in which case you should seek advice from your doctor or contact the Poisons Information Centre on 0800 764 766).

**Side effects**

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by ULTRAPROCT®.

If ULTRAPROCT® is applied for long periods of time (more than 4 weeks), local concomitant symptoms, such as atrophy of the skin cannot be excluded.

Allergic skin reactions may occur in rare cases.

**Storage**

Do not use after the expiry date stated on the package.

Store all drugs properly and keep them out of reach of children.

Ultraproct® Ointment should be stored below 25°C.

Ultraproct® Suppositories should be stored in the fridge (at 2°C to 8°C). Do not freeze.

**Further information**

Additional specific therapy is required in fungal infections.

Care must be taken that ULTRAPROCT® does not come into contact with the eyes. Careful hand washing after use is recommended.

If you have any further questions please consult your doctor or pharmacist.
Sponsor

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Date of preparation

This leaflet was prepared in May 2012.