SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ultraproct® Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains:

Fluocortolone pivalate BP 0.6 1mg

Fluocortolone hexanoate BP 0.63mg

Cinchocaine hydrochloride BP 1.00mg

3 PHARMACEUTICAL FORM

Suppository

Each suppository is white.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of haemorrhoids and of pruritus ani in the short term (5-7 days).

4.2 Posology and method of administration

One suppository to be inserted daily. In severe cases, one suppository two to three times daily at the beginning of treatment. The suppositories should be inserted after defaecation.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1. Viral infections. Primary bacterial or fungal infections. Secondary infections of the skin in the absence of appropriate anti-infective therapy. Known sensitivity to local anaesthetics.

4.4 Special warnings and precautions for use

In infants, long-term continuous therapy with topical corticosteroids should be avoided.

Occlusion is not appropriate on the perineum. Adrenal suppression can occur even without occlusion. The application of unusually large quantities of topical corticoids may result in the absorption of systemically active amounts of corticoid.

Secondarily-infected dermatoses definitely require additional therapy with antibiotics or chemotherapeutic agents. This treatment can often be topical but for heavy infections systemic antibacterial therapy may be necessary. If fungal infections are present, a topically active anti-mycotic should be applied.

Ultraproct should not be allowed to come into contact with the eyes. Patients should be advised to wash their hands carefully after use.

4.5 Interaction with other medicinal products and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects on the human foetus.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

As with all topical steroids there is a risk of developing skin-atrophy following extensive therapy.

Allergic skin reactions may occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ultraproct contains the steroids fluocortolone hexanoate and fluocortolone pivalate, and the topically active local anaesthetic, cinchocaine hydrochloride.

Fluocortolone hexanoate: A topically active corticosteroid with the powerful anti-inflammatory properties of fluocortolone. Although its action is in less rapid onset than that of fluocortolone pivalate, it is more prolonged.

Fluocortolone pivalate: A rapid-acting ester of fluocortolone.

Cinchocaine hydrochloride: Has a local anaesthetic effect on mucous membranes and in combination with the above steroids provides quick relief of the painful and pruritic symptoms

5.2 Pharmacokinetic properties

Absorption and distribution: No data are available on the rectal absorption of fluocortolone hexanoate. The extent of the rectal absorption of fluocortolone pivalate is approximately 5% of the dose.

Metabolism: In-vitro and in-vivo investigations with corticosteroid esters (halogenated and non-halogenated corticoids) have shown that these compounds are split extremely rapidly into the corticoid and fatty acid through the esterases which are ubiquitously present in the body.

Elimination: No specific data are available on the elimination of fluocortolone hexanoate or fluocortolone pivalate in humans. However, it is known that corticosteroid metabolites are excreted in the urine.

5.3 Preclinical safety data

There are no preclinical safety data which could be of relevance to the prescriber and which are not already included in other relevant sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard fat

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a refrigerator.

6.5 Nature and contents of container

Packs of 12 (OP)

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Meadow Laboratories Limted

Unit 13, Falcon Business Centre

Ashton Road

Romford

Essex RM3 8UR
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 19115/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

04/04/1989 / 26/03/2002

10 DATE OF REVISION OF THE TEXT

11/08/2017