

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Proctosedyl Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cinchocaine Hydrochloride (micro) BP 5mg

Hydrocortisone (micro) EP 5mg

3 PHARMACEUTICAL FORM

Smooth off-white suppositories.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The local anaesthetic Cinchocaine relieves pain and relaxes sphincteric spasm. Pruritis and inflammation are relieved by Hydrocortisone which also decreases serous discharge. Proctosedyl is, therefore, useful for the short term relief (not more than 7 days) of pain, irritation and pruritis associated with haemorrhoids, pruritis ani.

4.2 Posology and method of administration

Adults (including the elderly) and children:

A suppository is inserted morning and evening, and after each stool. The ointment may be used concurrently with the suppositories.

4.3 Contraindications

Known hypersensitivity to any of the ingredients. Not for use in the presence of infections.

4.4 Special warnings and precautions for use

As with all preparations containing topical steroids, the possibility of systemic absorption should be considered. In particular, long-term continuous therapy should be avoided in infants. Adrenal suppression can occur even without occlusion.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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 Fertility, Pregnancy and lactation

In pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.

Hydrocortisone may pass into human breast milk. Given the possible maternal systemic absorption and lack of data, Proctosedyl Suppositories should preferably not be used during lactation unless the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10\ 000$ to $< 1/1000$); very rare ($< 1/10\ 000$), not known (cannot be estimated from the available data).

Eye disorders

Not known: Chorioretinopathy, blurred vision (see also section 4.4)

Endocrine disorders:

Not known: Adrenal suppression.

Skin and subcutaneous disorders:

Not known: Urticaria, Rash.

In persons sensitive to any of the ingredients, anal irritation 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cinchocaine is a local anaesthetic of the amide type.

Hydrocortisone is a glucocorticoid with anti-inflammatory and other properties.

5.2 Pharmacokinetic properties

The literature states that absorption of Hydrocortisone does occur through the skin, particularly denuded skin. However, this absorption is not of a clinical significance as Hydrocortisone topically has only rarely been associated with side effects resulting from pituitary adrenal suppression.

Cinchocaine is little absorbed through the intact skin, but absorbed through mucous membranes. Like other local anaesthetics of the amide type, Cinchocaine is metabolised in the liver.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hard fat

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store at 2°C – 8°C.

6.5 Nature and contents of container

Each suppository is contained in a pocket formed from white PVC/PE laminate in packs of 12.

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 53886/0070

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
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17/08/2010

10 DATE OF REVISION OF THE TEXT

01/11/2021