Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Proctosedyl Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 5 mg of Hydrocortisone, 5 mg of Cinchocaine Hydrochlroide, 10 mg of Aesculin and 10 mg of Framycetin Sulphate.

Excipients - Contains wool fat 10% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.

Yellowish white, translucent, homogeneous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

In the local management of pain, pruritus and inflammation associated with internal or external haemorrhoids, and such haemorrhoidal complications as fissures, proctitis, perianal eczema, and post-operative states.

4.2 Posology and method of administration

Dosage:

Application to external surface or by means of the cannula into the rectum, twice daily and after each bowel movement. Treatment should last for a week.

Administration:

Topical, Intrarectal and Perianal

4.3 Contraindications

1. Use in the presence of untreated infections of viral, bacterial, tuberculous, parasitic or fungal origin.

2. Use in patients hypersensitive to the active ingredient or any of the excipients.

4.4 Special warnings and precautions for use

Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression and growth retardation.

Continuous application without interruption will result in local atrophy of the skin, striae, and superficial vascular dilation.

Prolonged use of an anti-infective may result in the development of super-infection due to organisms, including fungi, resistant to that anti-infective.

May cause local skin reactions (e.g. contact dermatitis).

Before prescribing the product any potential malignancies should be excluded.

Pheochromocytoma crisis, which can be fatal, has been reported after administration of corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation (see section 4.8)

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.

Hydrocortisone may pass into human breast milk.

This product should not be used in pregnancy or lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Itching, pain or rash may develop around the back passage.

Skin and subcutaneous disorders:
Frequency not known: Urticaria, contact dermatitis, rash.

Endocrine disorders:
Frequency not known: Pheochromocytoma crisis, adrenal suppression.

Eye disorders:
Vision blurred (see also section 4.4).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

In the rare event of overdosage, supportive and symptomatic therapy is indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: CO5A

A combination of a glucocorticoid, local anaesthetic and antibacterial.

5.2 Pharmacokinetic properties

None Stated.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool fat (lanolin)
Liquid paraffin
White soft paraffin.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened - 3 years
In use shelf life - 4 weeks

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tubes internally lacquered with cannula attachment. Pack sizes are 15g and 30g. Each tube is accompanied by a cannula attachment.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath.
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/029/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1978

Date of last renewal: 25th November 2009

10 DATE OF REVISION OF THE TEXT

December 2023