RECTO / FRONT

CCL	**NOM DU PRODUIT / PRODUCT NAME:** INSERT PHOENIX PROCTOSEDYL ON MY UNF **NUMÉRO DU PRODUIT/PRODUCT NUMBER:** 20005319A **Nº CODE À BARRES / BARCODE NO.:** 20005319A
	APPROBATION / APPROVAL **BAUSCH HEALTH COMPANIES INC LAVAL**

SPÉCIFICATIONS

TYPE ET POIDS DE PAPIER / PAPER TYPE AND WEIGHT: 54M (27#) OFFSET
DIMENSIONS (MM): À PLAT / FLAT: 180 X 192
PLIÉ / FOLDED: N/A
POINTS DE COLLE / GLUE SPOTS: N/A
FEUILLET PLIÉ / FOLDED LEAFLET: ANGLAIS/ENGLISH VISIBLE

SIGNATURE / DATE

COULEUR(S) / COLOR(S)

#1 PANTONE Reflex Blue U

ÉPREUVES DE L'IMPRIMEUR / VENDOR'S PROOF DATE: 2024-01-19 INITIALES: _____

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Proctosedyl®

Ointment
Cinchocaine Hydrochloride
Hydrocortisone
Framycetin Sulphate
Aesculin

20005319A

PHOENIX LABS

Presentation

Proctosedyl is available as an odourless, yellowish white, translucent, greasy ointment. Each gram of ointment contains the following active ingredients:

Cinchocaine Hydrochloride 5mg
Hydrocortisone 5mg
Framycetin Sulphate 10mg
Aesculin 10mg

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics)

Framycetin Sulphate

Framycetin Sulphate is administered topically in the treatment of infections of the skin due to susceptible organisms such as Staphylococci. Application to the skin have been reported to produce no detectable levels in the blood and urine or sufficient absorption to cause systemic toxicity. However, application to areas of denuded skin (e.g. in serious burns) has resulted in significant absorption and it has been reported to occur from wounds and inflamed skin. Once absorbed, it is rapidly excreted by the kidneys in the active form: 30-50% of a parenteral dose has been detected in the urine.

Due to its known toxicological profile contraindicating its parenteral use and its excellent activity, Framycetin is well suited for topical use.

Hydrocortisone

Hydrocortisone is absorbed through the skin, particularly in denuded areas when applied topically. It acts locally as an anti-inflammatory agent. When absorbed systematically, it has a biological half-life of about 100 minutes and is more than 90% bound to plasma proteins. It is metabolized in the liver and most body tissues to hydrogenated and degraded forms which are then excreted in the urine as glucuronides with a small proportion of unchanged Hydrocortisone.

Cinchocaine Hydrochloride

Cinchocaine Hydrochloride is a local anaesthetic suitable for surface anaesthesia. It has a more prolonged action than Lignocaine. Like other local anaesthetics of the amide type it is metabolized in the liver.

Aesculin

Aesculin is used for external application only.

Uses

The local anaesthetic cinchocaine relieves pain and relaxes sphincteric spasm. Pruritus and inflammation are relieved by hydrocortisone, which also decreases serous discharge, while Framycetin Sulphate controls local infection (a cause of inflammation and irritation). Proctosedyl is thus used for the following: internal and external haemorrhoids; prophylaxis between attacks to prevent recurrences; haemorrhoidal complications-anal pruritus, perianal eczema, proctitis, fissure; pre-operative and post-operative treatment of haemorrhoidectomy patients; post-partum haemorrhoidal conditions.

Dosage and administration

Apply the ointment in small quantity with the finger, on the painful or pruritic area, morning and evening and after each stool. For deep application attach cannula to tube, insert to full extent and squeeze tube gently from lower end whilst withdrawing. The ointment may be used separately or concurrently with the suppositories.

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COULEUR(S) / COLOR(S) #1 PANTONE Reflex Blue U		**SIGNATURE / DATE**
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Contra-indications, warning, etc.
Use in the presence of untreated infections of viral, bacterial, tuberculous, parasitic or fungal origin. Known hypersensitivity to any of the ingredients. 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. This product should not be used in pregnancy or lactation unless considered essential by the physician. As with all preparations containing topical corticosteroids, the possibility of systemic absorption should be considered. In particular, long-term continuous therapy should be avoided in infants. Adrenal suppression and growth retardation can occur even without occlusion.

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

Before prescribing the product any potential malignancies should be excluded.

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.

Interaction with other medicaments
None stated

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

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

Storage Condition
Store below 30°C (protect from excessive heat).

Package quantities
Proctosedyl Ointment: Tubes of 15g

Shelf-life
Do not use later than the expiry date indicated on the packaging.

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Manufacturer
Bausch Health Companies Inc.,
2150 St. Elzear Blvd. West, Laval, Quebec, H7L 4A8, Canada.

Date of Revision
February 2024

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