

PRESCRIBING INFORMATION

PROCTOSEDYL®

(Hydrocortisone BP - Framycetin sulfate BP -
Cinchocaine hydrochloride BP - Aesculin)

Anorectal Therapy

APTALIS PHARMA CANADA INC.	Version Date:
597 Laurier Blvd.	April 26, 2012
Mont-St-Hilaire, Quebec	
Canada J3H 6C4	Control Number: 154596

PRESCRIBING INFORMATION**NAME OF DRUG**PROCTOSEDYL[®]

(Hydrocortisone BP - Framycetin sulfate BP -
Cinchocaine hydrochloride BP - Aesculin)

THERAPEUTIC CLASSIFICATION

Anorectal Therapy

Indications:

The reduction of swelling, pain and inflammation of hemorrhoids and other rectal lesions. The management of acute and chronic nonspecific proctitis, acute internal hemorrhoids, cryptitis, fissures and incomplete fistulas, internal and external pruritus ani. May be used in pre- and postoperative hemorrhoidectomy and repair of fissures.

Contraindications:

Hydrocortisone must not be used in the presence of tuberculosis, fungal and viral infections. Sensitivity to any of the components.

Precautions:

Discontinue use if sensitization occurs. Hydrocortisone should not be used until an adequate proctologic examination is completed and a diagnosis made. Other specific measures against infections, allergy, and other causal factors must not be neglected. The possibility, however rare, that prolonged use of this preparation might produce systemic corticosteroid effects, should be borne in mind. Patients should be advised to inform subsequent physicians of the previous use of hydrocortisone.

The safe use of topical corticosteroids during pregnancy has not been fully established. Therefore, during pregnancy, they should not be used unnecessarily on extended areas, in large amounts or for prolonged periods of time.

Adverse Effects:

Certain patients may experience the following adverse effects:

Gastrointestinal disorders: anal pruritus, anorectal discomfort, proctalgia

General disorders and administration site conditions: burning, irritation and pain at the application site

Immune system disorders: hypersensitivity manifested as pruritus, rash and/or urticaria

Dosage:**Ointment:**

For external treatment: apply a small quantity morning and evening and after each bowel movement to the affected area. For internal application: attach rectal cannula to tube, insert to full extent and squeeze tube gently from lower end while withdrawing.

Suppositories:

One suppository morning and evening and after each bowel movement.

Supplied:

Each rectal suppository or gram of ointment contains: hydrocortisone BP 5 mg (0.5%), framycetin sulfate BP 10 mg (equivalent to 7 mg of framycetin base-1%), cinchocaine hydrochloride BP 5 mg (0.5%), aesculin 10 mg (1%). The ointment contains 10% w/w anhydrous lanolin. Ointment, tubes of 15 and 30 g with rectal cannula; suppositories, boxes of 12 and 24. Store between 15° and 30°C.

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