

PRESCRIBING INFORMATION
Including Patient Medication Information

PROCTOSEDYL[®]

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

Anorectal Therapy

APTALIS PHARMA CANADA ULC	Version Date:
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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.

PROCTOSEDYL contains an antibacterial ingredient, framycetin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of framycetin, PROCTOSEDYL should only be used for the authorized indication and clinical use.

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.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing PROCTOSEDYL in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

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.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PROCTOSEDYL®
Hydrocortisone, framycetin sulfate, cinchocaine hydrochloride and aesculin ointment / suppositories

Read this carefully before you start taking **Proctosedyl** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Proctosedyl**.

What is Proctosedyl used for?

- To reduce the swelling and pain of hemorrhoids.
- To reduce the swelling and pain of sores on your rectum or anus.
- To treat swelling irritation, itching and cracking of the rectum and anus.
- Proctosedyl contains an antibacterial ingredient called framycetin sulfate, and it should be used exactly as directed by your healthcare professional.

How does Proctosedyl work?

Proctosedyl contains the following medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride and aesculin. Hydrocortisone is a steroid medicine. Framycetin sulfate is an antibiotic. Cinchocaine hydrochloride is a pain medicine. Aesculin protects the blood vessels. These work together to reduce swelling and pain and to relieve itching.

What are the ingredients in Proctosedyl?

Medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride, aesculin

Non-medicinal ingredients: anhydrous lanolin (ointment only)

Proctosedyl comes in the following dosage forms:

5 mg hydrocortisone, 10 mg framycetin sulfate, 5 mg cinchocaine HCl, 10 mg aesculin per gram of ointment or per suppository.

Do not use Proctosedyl if you:

- Have tuberculosis
- Have a fungal infection
- Have a viral infection
- Are sensitive to any of the ingredients in Proctosedyl

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Proctosedyl. Talk about any health conditions or problems you may have, including if you:

- Have been using another product that contains hydrocortisone
- Are pregnant

Other warnings you should know about:

Tell your healthcare professional if you get any sensitivity while using Proctosedyl.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Proctosedyl:

Ointment:

- External treatment:
 - Apply a small quantity to the affected area in the morning and in the evening and after every bowel movement.
- Internal treatment:
 - Attach the rectal cannula to the tube,
 - insert cannula into rectum to full extent,
 - squeeze the tube gently from the lower end while removing it from your rectum.
 - Apply in the morning and evening and after every bowel movement.

Suppositories:

- Insert one suppository into your rectum in the morning and in the evening and after every bowel movement.
- Misuse or overuse of Proctosedyl could lead to the growth of bacteria that will not be killed by framycetin sulfate. This means that Proctosedyl or other medicines containing framycetin sulfate may not work for you in the future.
- Do not share your medicine.

Usual dose:

A small quantity of ointment or one suppository in the morning and evening and after each bowel movement.

Overdose:

If you think you have taken too much Proctosedyl, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to apply Proctosedyl, apply it when you remember.
- Then, continue to apply in the morning and evening and after every bowel movement.

What are possible side effects from using Proctosedyl?

These are not all the possible side effects you may feel when taking Proctosedyl. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Discomfort, irritation or pain of the anus
- Discomfort or pain of the rectum
- Burning, irritation or pain at the application site
- Itching
- Rash

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15° and 30° C.

If you want more information about Proctosedyl:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.allergan.ca, or by calling 1-800-866-6424.

This leaflet was prepared by Aptalis Pharma Canada ULC

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