

**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](http://www.allergan.ca), or by calling 1-800-866-6424.

This leaflet was prepared by Aptalis Pharma Canada ULC

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