

Proctosedyl® Ointment

Hydrocortisone/Cinchocaine hydrochloride/Framycetin sulphate/Aesculin

Is this leaflet hard to see or read? Phone +353 1 5742410 for help.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Proctosedyl ointment is and what it is used for
2. What you need to know before you use Proctosedyl ointment
3. How to use Proctosedyl ointment
4. Possible side effects
5. How to store Proctosedyl ointment
6. Contents of the pack and other information

1. What Proctosedyl ointment is and what it is used for

The name of your medicine is Proctosedyl ointment. Proctosedyl ointment contains four different medicines called: hydrocortisone 5mg, Cinchocaine hydrochloride 5mg, Framycetin Sulphate 10 mg and Aesculin 10mg.

- Cinchocaine hydrochloride belongs to a group of medicines called local anaesthetics. It works by causing numbness in the area to which it is applied. This stops you feeling pain in this area and helps lessen the spasm of the back passage.
- Hydrocortisone belongs to a group of medicines called corticosteroids. It works by lowering the production of substances that cause inflammation. This helps lower swelling, itching and discharge.

Proctosedyl ointment can be used for the short-term relief (not more than 7 days) of:

- Pain, irritation, discharge and itching associated with enlarged or swollen blood vessels around your back passage (haemorrhoids).
- Itching around your back passage.

2. What you need to know before you use Proctosedyl ointment

Do not use this medicine and tell your doctor if:

- You are allergic (hypersensitive) to hydrocortisone, cinchocaine hydrochloride, framycetin sulphate, aesculin or any of the other ingredients of Proctosedyl ointment (listed in Section 6 below).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have any kind of infection.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Proctosedyl.

Warnings and Precautions

Talk to your doctor or pharmacist before using Proctosedyl Ointment if you have an adrenal gland tumour (pheochromocytoma).

Contact your doctor if you experience blurred vision or other visual disturbances.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Proctosedyl can affect the way some other medicines work. Also some medicines can affect the way Proctosedyl works.

Some medicines may increase the effects of Proctosedyl and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Proctosedyl Ointment has no effect on your ability to drive or use any tools or machines.

Important information about some of the ingredients of Proctosedyl ointment

This medicine contains wool fat (lanolin) which may cause local skin reactions such as contact dermatitis. Contact dermatitis causes redness, itching or irritation of the skin.

3. How to use Proctosedyl ointment

Always use Proctosedyl ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

- Do not use for longer than 7 days
- Only apply to your back passage and surrounding areas
- Do not apply to the face or other parts of the body
- Apply this medicine in the morning, evening and after each bowel movement
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How to apply this medicine

If your doctor has asked you to apply some ointment around your back passage and the surrounding area, follow the instructions below on how to apply this medicine:

- Wash your hands
- Squeeze a small amount of the ointment onto your fingertip

- Gently rub a small layer of ointment over the sore, painful or itching area
- Wash your hands

If your doctor has asked you to apply some ointment deeper into your back passage, follow the instructions below on how to apply this medicine:

- Wash your hands
- Screw the plastic nozzle provided onto the tube
- Insert the nozzle into the back passage
- Squeeze the tube gently as you slowly pull it out
- Stay still for 1 or 2 minutes
- Wash your hands and the nozzle

If you use more Proctosedyl ointment than you should

Let your doctor know if you have used this ointment for more than 7 days by mistake.

If you forget to use Proctosedyl ointment

If you forget to use your ointment, use it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Proctosedyl ointment can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if the following side effect gets serious or lasts longer than a few days, or you notice any side effects not listed in this leaflet:

- Itching, pain, rash around the back passage area
- Not known: frequency cannot be estimated from the available data:
- hives (urticaria)
 - blurred vision
 - pheochromocytoma crisis, a tumour of the adrenal gland, symptoms of which include high blood pressure, heavy sweating, fast heartbeat, shortness of breath
 - adrenal suppression: If you have used this ointment for a long time, it is possible that you could get something called 'adrenal suppression' and growth retardation, especially in children under the age of three. Signs of adrenal suppression include lack of appetite, pain in the stomach, weight loss, feeling sick or being sick, lack of concentration, a feeling of hunger, nervousness and fits.

Prolonged use of an anti-infective should be avoided as it may result in the development of a super infection due to organisms becoming resistant.

Corticosteroids can also worsen existing infection or cause new infection.

Continuous use may also cause local skin problems e.g. skin-thinning and striae (stretchmarks).

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance.

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Proctosedyl ointment

Keep out of reach and sight of children. Do not use Proctosedyl ointment after the expiry date which is stated on the label, carton or tube after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Once opened please use within 4 weeks.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Proctosedyl ointment contains

- Each gram of ointment contains 5 milligrams of the active substances cinchocaine hydrochloride, 5 milligrams of hydrocortisone, 10 milligrams of Framycetin Sulphate and 10mg of Aesculin.
- The other ingredients are wool fat (lanolin), liquid paraffin and white soft paraffin

What Proctosedyl ointment looks like and contents of the pack

Proctosedyl ointment is a yellowish-white translucent greasy ointment. It is available in a 30 gram aluminium tube with a plastic nozzle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Phoenix Labs,
Suite 12,
Bunkilla Plaza, Bracetown Business Park,
Clonee, Co. Meath,
Ireland.
Tel: +353 1 5742410
email: medicalinformation@phoenixlabs.ie

Manufacturer

Sanofi Winthrop Industrie
196 rue du Maréchal Juin
45200 Amilly
France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in December 2023