

PROCTOSEDYL® OINTMENT

Cinchocaine Hydrochloride / Hydrocortisone / Framycetin Sulphate / Aesculin (5mg/ 5mg/ 10mg/ 10mg)

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What Proctosedyl Ointment is used for

Proctosedyl Ointment can be used for short term relief of:

- Pain, irritation, discharge and itching related with enlarged or swollen vessels around your back passage (haemorrhoids)
- Pre and post-surgery to remove haemorrhoid.
- Postnatal (after given birth) haemorrhoidal conditions.

How Proctosedyl Ointment works

Proctosedyl Ointment contain four different medicines called: Hydrocortisone, Cinchocaine Hydrochloride, Framycetin Sulphate and Aesculin.

- 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 spasms 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.
- Framycetin Sulphate belongs to a group of medicines called antibiotics. It used to treat local infections.

Before you use Proctosedyl Ointment

-When you must not use it

Do not use Proctosedyl Ointment if:

- You are allergic (hypersensitive) to Cinchocaine Hydrochloride,

hydrocortisone or to any of the other listed ingredients.

- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue.

- You are pregnant

- 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 Ointment.

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.

-Before you start to use it

Please confirm if:

- You are not allergic (hypersensitive) to any of the listed ingredients.
- You are not pregnant

If you are not sure whether you are suitable to apply Proctosedyl Ointment, talk to your doctor or pharmacist before using Proctosedyl Ointment.

-Taking other medicines

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

How to use Proctosedyl Ointment

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

- Wash your hand with soap before and after applying the ointment.
- Apply the ointment in small quantity with your finger over the sore, painful or itching area.

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

- Wash your hand with soap before and after applying the ointment.
- Screw the plastic nozzle provided onto the tube
- Insert the nozzle into your back passage and squeeze the tube gently as you slowly pull it out from your back passage.
- Wash your nozzle with soap after applying your ointment.

-How much to use

Use this medicine in the morning, evening and after each bowel movement.

-When to use it

Use Proctosedyl Ointment at about the same time each day unless your doctor tells you otherwise.

-How long to use it

Ask your doctor or pharmacist if you are not sure how long to use the medicine for.

-If you forget to use it

- 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.

-If you use too much (overdose)

If you use Proctosedyl Ointment more than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do

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.

-Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop using Proctosedyl Ointment, or change the dosage, without checking with your doctor.

-Things to be careful of

Driving and using machines
Proctosedyl Ointment is unlikely to affect your ability to drive or operate machinery. However, do not drive or operate any machinery if you are feeling unwell.

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.

Side Effect

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 available data:

- hives (urticaria)
- blurred vision
- pheochromocytoma crisis, a tumor 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 (stretch marks).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Proctosedyl Ointment

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

-Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Proctosedyl Ointment after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 30°C (protect from excessive heat).

-Disposal

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.

Product Description

What it looks like

Proctosedyl Ointment is an odourless yellowish-white translucent greasy ointment. It is available in a 15g tubes.

Ingredients:

- Active ingredients are Cinchocaine Hydrochloride, Hydrocortisone, Framycetin Sulphate, Aesculin
- Inactive ingredients are wool fat, liquid paraffin and white soft paraffin.

MAL Numbers:

MAL19871349ACZ

Manufacturer

Bausch Health Companies Inc.

2150 St. Elzear Blvd West, Laval, Quebec, H7L 4A8, Canada.

Product Registration Holder

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