

PACKAGE LEAFLET: INFORMATION FOR THE USER

Proctosedyl Suppositories

Cinchocaine hydrochloride 5mg
Hydrocortisone 5mg

SANOFI

 **Is this leaflet hard to see or read?**
Phone 0800 035 2525 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 if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

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

1. What Proctosedyl Suppositories are and what they are used for



The name of your medicine is Proctosedyl Suppositories. Proctosedyl Suppositories contain two different medicines called: cinchocaine hydrochloride and hydrocortisone.

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

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

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



Do not take use this medicine and tell your doctor if:

You are allergic (hypersensitive) to cinchocaine hydrochloride, hydrocortisone or any of the other ingredients of Proctosedyl Suppositories (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 Suppositories

Warnings and precautions

Talk to your doctor or pharmacist before using Proctosedyl Suppositories.

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



Other medicines and Proctosedyl Suppositories

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Proctosedyl Suppositories and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

This is because Proctosedyl Suppositories can affect the way some other medicines work. Also some medicines can affect the way Proctosedyl Suppositories works.

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.

3. How to take Proctosedyl Suppositories

Always take Proctosedyl Suppositories 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 insert into your back passage
- Insert one suppository in the morning, evening and after each bowel movement
- Wash your hands before and after inserting the suppository

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- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

If you take more Proctosedyl Suppositories than you should

Let your doctor know if you have used the suppositories for more than 7 days by mistake. If you accidentally insert too many suppositories or a suppository is swallowed, contact your doctor or pharmacist immediately.

If you forget to use Proctosedyl Suppositories

If you forget to use your suppository, insert it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not insert more than one suppository 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 Suppositories 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 if you notice any side effects not listed in this leaflet:

- Itching or burning sensation around the back passage area
- Skin rash
- Blurred vision

If you have used Proctosedyl Suppositories for a long time, it is possible that you could get something called ‘adrenal suppression’. Signs 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.

Reporting of 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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Proctosedyl Suppositories

Keep this medicine in a safe place where children can not see or reach it.

Do not use Proctosedyl Suppositories after the expiry date which is stated on the label or carton after EXP.

The expiry date refers to the last day of that month. Store at 2°C - 8°C.

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 Suppositories contain

- Each suppository contains 5 milligrams of the active substance, cinchocaine hydrochloride and 5 milligrams of the active substance hydrocortisone
- The other ingredient is hard fat

What Proctosedyl Suppositories look like and contents of the pack

The suppositories are smooth and off-white in colour. Proctosedyl Suppositories are available in packs of 12. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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.

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