

PROCTOSEDYL[®]

Hydrocortisone and cinchocaine hydrochloride

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about PROCTOSEDYL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PROCTOSEDYL is used for

PROCTOSEDYL Ointment and Suppositories are used for the relief of the discomfort of haemorrhoids (piles) and other painful conditions of the anus (rear end), such as fissures (tears). Haemorrhoids often result when people strain while trying to open their bowel (defecate). This problem is often, but not always, associated with low-fibre diets.

PROCTOSEDYL Ointment and Suppositories contain the active ingredients hydrocortisone, a steroid, and cinchocaine hydrochloride, a local anaesthetic. These work together to reduce swelling, numb pain and relieve itching.

Your doctor or pharmacist, however, may recommend PROCTOSEDYL for another purpose.

Ask your doctor or pharmacist if you have any questions about why it has been recommended for you.

Before you use it

When you must not use it

Do not use PROCTOSEDYL if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

As for all steroid preparations, do not use PROCTOSEDYL when infections affecting the anus or surrounding area are present eg sexually-transmitted diseases such as herpes.

PROCTOSEDYL use may hide signs of infection.

Do not use PROCTOSEDYL if you have tuberculosis.

Some diseases can be made worse by using PROCTOSEDYL.

Do not give PROCTOSEDYL to children under 12 years of age.

Do not use it after the expiry date (EXP) printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn/damaged or shows signs of tampering.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- cuts or abrasions in the area of the anus eg if there is blood on toilet paper or in the toilet after opening the bowels (defecating). Your doctor or pharmacist will need to consider this when

recommending treatment with PROCTOSEDYL.

- **fungal infections such as thrush, in the area of the anus.** PROCTOSEDYL does not treat these conditions. Your doctor or pharmacist may need to provide treatment for these conditions.
- severe or prolonged anal pain or if blood is present in the faeces, in which case you should have a doctor examine the area.

Tell your doctor or pharmacist if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you use PROCTOSEDYL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

These medicines may be affected by PROCTOSEDYL, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

How to use it

How much to use

The standard dose for this medicine is up to three times a day (eg after your morning bowel motion, noon and evening) or as your doctor or pharmacist tells you.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to use.

Follow the instructions they give you.

If you use the wrong dose, PROCTOSEDYL may not work as well and your problem may not improve.

How to use it

For best results, first go to the toilet and empty your bowels. Do not strain. Wash and dry the anal area.

Before and after use, wash your hands well with soap and water.

Ointment:

1. If the affected area is on the surface, use your finger to apply just enough ointment to cover the painful area.
2. If you need to apply PROCTOSEDYL Ointment deeper, first screw the plastic nozzle & cap (which are supplied in the carton) tightly on to the tube, removing the cap immediately before use.
3. Then gently insert the nozzle all the way into the rectum (back passage) and squeeze the tube from the lower end, while at the same time withdrawing it from the rectum.
4. After use, wash the nozzle with warm, soapy water then recap the nozzle.

Note that if the area is very inflamed and painful, it is advisable to initially apply the ointment with a finger, rather than insert the nozzle.

Suppositories:

1. Remove the suppository from its packaging.
2. Moisten the suppository by dipping it briefly in cool water.
3. Put one foot on the side of the bath or toilet, raising the knee to the chest.
4. Insert the suppository gently into the rectum (back passage).
5. Try not to go to the toilet for at least one hour to allow the suppository time to work.

PROCTOSEDYL should not be used by children under 12 years of age.

How long to use it

If you bought PROCTOSEDYL without a doctor's prescription, you should check with your doctor

if you need to use it for more than 7 days.

PROCTOSEDYL should be used three times daily for first week, after morning stool, noon and evening.

If you use it for longer than 7 days, then you may be able to reduce the number of times you have to use it each day.

During your second week of use, you may be able to use PROCTOSEDYL twice a day after morning stool and evening, and then once daily in your third week of use after morning stool.

Unless your doctor advises differently, you should not use PROCTOSEDYL continuously for longer than three weeks.

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

If you use too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have used too much PROCTOSEDYL.

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

Tell your doctor or pharmacist if the use of PROCTOSEDYL causes increased discomfort or a rash around the anus.

If you find that your condition persists despite using PROCTOSEDYL, seek advice from your doctor or pharmacist.
Tell all the doctors, dentists and pharmacists who are treating you

that you are using PROCTOSEDYL.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using PROCTOSEDYL.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using this medicine.

Things you must not do

Do not use more than the recommended dose unless your doctor or pharmacist tells you to.

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 or pharmacist tells you to.

Things to be careful of

It is not known if PROCTOSEDYL adversely affects latex rubber condoms. Thus it is recommended that you avoid contact between latex rubber condoms and PROCTOSEDYL.

Things that may help your condition

Some self-help measures suggested below may help your condition.

Talk to your doctor or pharmacist about them.

- **Do not strain while trying to open your bowels.** Straining may aggravate haemorrhoids.
- **Increasing the amount of fibre in the diet may reduce your chance of getting haemorrhoids.** This can be achieved by eating more fruit, salads, vegetables and cereals containing bran. It may also be helpful to drink plenty of non-alcoholic fluids and exercise regularly.

Side effects

All medicines have some unwanted side effects. Sometimes they are

serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PROCTOSEDYL.

It helps most people with haemorrhoids, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice:

- an uncomfortable burning sensation in the anal area.

This is a mild side effect of this medicine and usually short-lived.

If any of the following happen, stop using this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to PROCTOSEDYL. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After using it

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 PROCTOSEDYL Ointment in a cool, dry, dark place where the temperature stays below 25°C.

Keep PROCTOSEDYL Suppositories at 2 °C to 8°C. Refrigerate. Do not freeze.

Do not store these medicines in the bathroom, near a sink, or on a window sill.

Do not leave these medicines in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop using PROCTOSEDYL, or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

PROCTOSEDYL comes in two presentations:

- PROCTOSEDYL Ointment is an odourless yellowish-white translucent greasy ointment
- PROCTOSEDYL Suppositories are smooth, white suppositories contained in a blister strip

PROCTOSEDYL Ointment is available in 15 g and 30 g tubes.

PROCTOSEDYL Suppositories are available in blister packs of 12 suppositories.

Ingredients

PROCTOSEDYL Ointment:

Active Ingredients:

- hydrocortisone 5 mg/g and cinchocaine hydrochloride 5 mg/g

Inactive Ingredients:

- liquid paraffin
- white soft paraffin
- wool fat

PROCTOSEDYL Suppositories

Active Ingredients:

- hydrocortisone 5 mg and cinchocaine hydrochloride 5 mg per suppository

Inactive Ingredients:

- hard fat

PROCTOSEDYL does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

PROCTOSEDYL is supplied in Australia by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

PROCTOSEDYL is supplied in New Zealand by:

sanofi –aventis new zealand limited
Level 8, James and Wells Tower
56 Cawley Street
Ellerslie
Auckland

This leaflet was prepared in May 2010.

Australian Register Numbers

Ointment: AUST R 21847

Suppositories: AUST R 22614

® Registered Trademark