PROCTOSEDYL ® SUPPOSITORY

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

What is in this leaflet

- 1. What Proctosedyl Suppository is used for
- 2. How Proctosedyl Suppository works
- 3. Before you use Proctosedyl Suppository
- 4. How to use Proctosedyl Suppository
- 5. While you are using it
- 6. Side effects
- Storage and Disposal of Proctosedyl Suppository
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What Proctosedyl Suppository is used for

Proctosedyl Suppository 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 Suppository works

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

Before you use Proctosedyl Suppository

-When you must not use it

Do not use Proctosedyl Suppository if:
• You are allergic (hypersensitive) to

- Cinchocaine Hydrochloride, hydrocortisone or to any 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

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 Suppository.

-Before you start to use it

Please confirm if:

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

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

-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 Suppository can affect the way some medicines work. Also some medicines can affect the way Proctosedyl Suppository work.

How to use Proctosedyl Suppository

- Wash your hand with soap before and after inserting the suppository.
- Only insert into your back passage.

-How much to use

- Use this medicine in the morning, evening and after each bowel movement.
- The Proctosedyl Suppository may be used separately or concurrently.

-When to use it

Use Proctosedyl Suppository 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 suppository, 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 Suppository 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 Suppository, or change the dosage, without checking with your doctor.

-Things to be careful of

Driving and using machines

Proctosedyl Suppository is unlikely to affect your ability to drive or operate machinery. However, do not drive or operate any machinery if you are feeling unwell.

Side Effect

Like all medicines, Proctosedyl Suppository can cause side effects, although not everyone gets them.

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

You may not experience any of them.

If you have used Proctosedyl Suppository for a long period of 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.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public →Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Proctosedyl Suppository

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 Suppository after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store at $2^{\circ}\text{C} \sim 8^{\circ}\text{C}$. Refrigerate. Do not freeze.

-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 Suppository are smooth and off-white in colour. They are available in packs of 12.

Ingredients:

 Active ingredients are Cinchocaine Hydrochloride, Hydrocortisone, Framycetin Sulphate, Aesculin • Inactive ingredients is Suppocire AM

MAL Numbers:

MAL19871350AZ

Manufacturer

PT Aventis Pharma, Jl. Jenderal A. Yani. Pulo Mas, Jakarta, Indonesia.

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18-1, Tower B, Plaza 33, No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

24/11/2017

Serial Number

NPRA(R4/1)081117/00308