DOPROCT RECTAL OINTMENT®

Hydrocortisone acetate/Benzocaine/Zinc oxide (5mg/10mg/200mg)

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What Doproct is used for

Doproct is used to treat:

• Pain, itchiness and inflammation due to the irritation in the anal e.g. haemorrhoids, fissures and postoperative haemorrhoid removal.

How Doproct works

Hydrocortisone is categorize under a group of corticosteroids. It has the properties of anti-inflammatory and anti-itching.

Benzocaine is a local anaesthetic that are used to block the sensory nerve endings in the skin.

Zinc oxide is used for soothing and protect against haemorrhoids.

Doproct is a product combination of hydrocortisone acetate, benzocaine and zinc oxide. These agents help to ease itchiness and thus allowing healing of the condition.

Before you use Doproct

- When you must not use it
- You have a history of hypersensitivity to active ingredients, hydrocortisone acetate, benzocaine or any other ingredients in Doproct.

If you are not sure whether you should start taking this medicine, consult your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- Have traumatised mucosa or sepsis (lifethreatening blood poisoning from infection) in anorectal region.
- Have not undergone adequate examination on colon, rectum, and anus.
- Have infections

Your doctor will perform an adequate examination and test to exclude probability of cancer, infections, allergy and other causal factors.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

- Aminosalicyclic acid (used to treat tuberculosis; bacterial infection that mainly affects the lungs.)
- Sulfonamides (antibiotic for ulcerative colon inflammation)

- Pregnancy and lactation

Doproct is unlikely to harm pregnant women. Hydrocortisone acetate released into breast milk are in small quantities and thus no significant harm on nursing infants. However, it is not recommended to be used on extended areas, in large amounts or for prolonged periods of time.

How to use Doproct

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

Apply a small amount of Doproct 2 times daily to the anal canal.

- When to use it

Apply it in the morning and evening after bowel movement.

- How long to use it

Continue to take your medicine as long as your doctor tells you.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Apply the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to apply the medicine and skip the missed dose. Do not apply a double dose to make up for the missed dose.

- If you use too much (overdose)

Consult your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have applied too much ointment. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

When using Doproct Rectal Ointment to the rectum, care should be taken to avoid the introduction of an excessive amount. It should be borne in mind that the systemic availability is relatively high with rectal administration, and large doses can cause effects on the central nervous system. Prolonged use of large doses of hydrocortisone can result in systemic effects or local effects such as skin thinning.

Contact sensitivity such as dry skin, itching, irritation, transient burning or stinging sensations may occur if Doproct Ointment is used excessively. Discontinue use if such symptoms occur.

While you are using it

- Things you must do
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are applying Doproct.
- If you are pregnant or plan to be pregnant, get advice from your doctor.
- <u>Things you must not do</u>
- Do not stop taking your medicines without consulting your doctor.
- Do not use Doproct after the expiry date which is stated on the carton and tube.

• Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

If irritation or rectal bleeding develops, the product should be discontinued.

Side effects

All medicines can have side effects. Doproct may cause unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice the following side effects:

- Dry skin
- Itching
- Irritation
- Transient burning or stinging sensations

Tell your doctor or pharmacist immediately if you notice the side effects gets serious or anything else that make you feel unwell.

Other side effects not listed above may also 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 Doproct

Storage

Keep medicines in original packaging. Store in cool (below 25° C), dry place, away from heat and light.

Do not leave your medicine in the car. Keep all medicines out of the reach of children.

- 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

Doproct is a white colored ointment.

- Ingredients

- Active ingredient

The ointment contains hydrocortisone acetate 5mg, benzocaine 10mg, and zinc oxide 200mg.

- Inactive ingredients

Purified water, mineral oil, glycerin, lactic acid, isopropyl myristate, methyl paraben, propyl paraben, and emulgade 1000 Ni T.

- Packing

Box of (1x10g) tube and box of (10x10g) tubes

- MAL Number

MAL07050013AZ

Manufacturer

Continental-Pharma Co. Ltd. 85/5 Soi Prachoomporn, Chaengwattana Road, Laksi, Bangkok 10210, Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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