

PACKAGE LEAFLET: Information for the user

ANTIHEMORROIDALE

Suppositories

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 only. 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 worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet

1. What Antihemorroidale suppositories are and what are they used for
2. What you need to know before you use Antihemorroidale suppositories
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1. WHAT ANTIHEMORROIDALE SUPPOSITORIES ARE AND WHAT ARE THEY USED FOR

Antihemorroidale is a local anesthetic and antiseptic which is used in the treatment of hemorrhoids.

The active ingredients of this medicine are: ephedrine hydrochloride, lidocaine hydrochloride, bismuth subgallate, zinc oxide, Peru balsam and castor oil.

Ephedrine hydrochloride decreases congestion due to its vasoconstrictor effect on the mucous membranes. Lidocaine hydrochloride is a local anaesthetic and its role in this medicine is to soothe pain in hemorrhoids. Bismuth subgallate has a protective effect of mucous membranes and a weak astringent and mild antiseptic effect. Zinc oxide in this medicine soothes local

irritation caused by hemorrhoids. Peru balsam has a mild antiseptic action. It is present in this medicine because it symptomatically soothes hemorrhoids. Castor oil is known for its laxative properties.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ANTIHEMORROIDALE SUPPOSITORIES

Do not use Antihemorroidale:

- if you are allergic to the active substances or to any of the other ingredients of this medicine.

Other medicines and Antihemorroidale

This medicine interacts with monoamine oxidase inhibitors (MAOIs), thus should not be used concomitantly with any agents of the MAOIs group.

Tell your doctor or pharmacist if you have any problems during the use of this medicine.

Pregnancy and breastfeeding

Lidocaine crosses placenta and is distributed into breast milk.

This suppository can be used during pregnancy and breastfeeding only under medical advice and control.

3. HOW TO USE ANTIHEMORROIDALE SUPPOSITORIES

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

This medicine is for rectal use only.

Dose:

1 suppository should be applied to the rectum. Up to 2 suppositories may be applied daily depending on the doctor's recommendation.

If there is no improvement within 3 days of treatment, consult your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Antihemorroidale suppositories can cause side effects, although not everybody gets them.

Hypersensitivity reactions, erythema or burning sensation in the skin may occur rarely.

If any of these side effects gets worse or if you experience side effects not listed in this leaflet, please contact your doctor or pharmacist. If you get any of the side effects mentioned above, discontinue treatment, and consult your doctor or pharmacist.

5. HOW TO STORE ANTIHEMORROIDALE SUPPOSITORIES

Keep this medicine out of the sight and reach of children.

Do not use Antihemorroidale suppositories after the expiry date which is stated on the packaging.

Store below 25°C, in a dry place!

6. OTHER INFORMATION

What Antihemorroidale contains

The active substances are ephedrine hydrochloride, lidocaine hydrochloride, bismuth subgallate, zinc oxide, Peru balsam, castor oil.

The excipients are colloidal anhydrous silica, hard fat.

Contents of the pack

Carton box with 10 suppositories.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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