Doxiproct® Local treatment of hemorrhoids

Composition

Calcium dobesilate: 40 mg, lidocaine hydrochloride: 20 mg, antiox. (E 320, E 310), macrogol 300, propyleneglycol. Excipients for 1 g of ointment.

Properties/ Effects

Calcium dobesilate acts on the capillary walls by regulating their impaired physiological functions - i.e. increased permeability and decreased resistance - and on different signs of inflammation. It also has an antithrombotic activity. Lidocaine hydrochloride, a local anesthetic, contributes to relieve pain. Doxiproct reduces inflammation, bleeding, oozing of serous fluids and brings a rapid relief of the signs and symptoms linked to inflammation of the anal region, such as pain, burning, pruritus and sensation of tension.

Pharmacokinetics

It is, however, known that the active principles contained in Doxiproct are partly resorbed by the skin.

Indications and usage

Internal and external hemorrhoids. Anal pruritus, anitis, perianitis, cryptitis, papillitis, acute hemorrhoidal thrombosis, anal fissures. Pre- and postoperative treatment in cases of hemorrhoidectomy

Dosage and administration

2 -3 times daily

In the morning and at bedtime apply, if possible after defecation, In cases of internal hemorrhoids, use the cannula by screwing it to the tube. Insert the cannula as deep as possible in the anus then press gently the tube while withdrawing it. In this case, the tube is sufficient for 10 applications. In case of external hemorrhoids or anal pruritus, apply a thin layer of the ointment several times a day.

The duration of the treatment is generally of some days. The doctor must be informed if, after 1 to 2 weeks of treatment, the symptomatology has not improved or has worsened.

The treatment should not be repeated without previous medical advice.

Limitations for use

Contraindication

Hypersensitivity towards the components of Doxiproct Children under 14

Precautions

In case of renal insufficiency, the application of Doxiproct should be limited to a few days.

In case of blood in the feces or its suspected presence, as well as of a simultaneous occurrence of pain and fever ,the physician must be consulted.

Treatment must be stopped in case of hypersensitivity reactions.

Pregnancy/Breast-feeding

Pregnancy category C: studies in pregnant women or animals are not available and, in humans, it is not known whether calcium dobesilate crosses the placental barrier. On the other hand, after topic administration, lidocaine hydrochloride are resorbed in variable quantities and can have systemic effects. Moreover, it crosses the placental barrier. In these conditions, Doxiproct should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus. After oral administration, calcium dobesilate is excreted in the maternal milk in low amounts, but it is not known whether this is the case with local use. After topic administration, lidocaine hydrochloride is excreted in the maternal milk. As a precaution, it should be decided between discontinuating the treatment or the breast-feeding.

Adverse reactions

Very rare cases have been reported: modifications of the intestinal transit, temporary burning sensation, local pain. Hypersensitivity reactions together with skin reactions and/or fever which may be of allergic origin and, can occur. (See" *Precautions*")

Interactions

No known up to now.

Overdosage

No case of overdosage known up to now,

Particular remarks

Storage

The ointment must be stored protected from heat. Doxiproct ointment should not be used after the expiration date printed on the package together with the mention "EXP".

Presentations

Ointment: tube of 30 q.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription ,the method of use and instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children



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