

110 mm

***Doxiproct*[®] plus**

Local treatment of hemorrhoids

Composition

Calcium dobesilate: 40 mg, lidocaine hydrochloride: 20 mg, dexamethasone acetate: 0,25 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. Dexamethasone acetate, a corticosteroid for topical use, possesses anti-inflammatory and antipruritic actions. Doxiproct Plus 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. The association of calcium dobesilate with a corticosteroid should be reserved for cases with marked inflammatory reactions. A long-lasting treatment is not indicated.

Pharmacokinetics

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

Indications and usage

Internal and external hemorrhoids. Anal pruritus, anal eczema. Anitis, perianitis, cryptitis, papillitis, acute hemorrhoidal thrombosis, anal fissure. 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, If the ointment is preferred, 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 8 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.

Limitations for use

Contraindication

Hypersensitivity towards the components of Doxiproct Plus.

Precautions

In case of renal insufficiency, Doxiproct Plus should not be used during longer periods. Avoid long-lasting treatments.

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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 and dexamethasone acetate are resorbed in variable quantities and can have systemic effects. Moreover, both substances cross the placental barrier. In these conditions, Doxiproct Plus 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 and dexamethasone acetate are 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 can occur. These reactions can be of allergic origin and, if it is the case, the treatment must be discontinued.

Interactions

No known up to now but, as a precaution, the interactions related to dexamethasone acetate should be taken into account.

Overdosage

No case of overdosage known up to now.

Particular remarks

Storage

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

Presentations

Ointment: tube of 30 g.



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