Proctosedyl
Hydrocortisone, Dibucaine hydrochloride, Neomycin B Sulfate, Esculoside

Suppository

SANOFI logo

Composition: Each suppository contains the following active
Ingredients:
Dibucaine hydrochloride.....5mg
Hydrocortisone.....5mg
Neomycin B sulfate.....10mg
Esculoside.....10mg

Identification:
Suppositories: smooth, off-white suppositories

Pharmacological action: The local anaesthetic dibucaine hydrochloride prevents or relieves the severe pain sometimes encountered in strangulated haemorrhoids, fissures and perianal haematomata, whilst the corticosteroid acts as a decongestant, anti-inflammatory and anti-pruritic agent and by so doing eliminates itching, inflammation and mucous discharge. The broad spectrum antibiotic, neomycin sulphate, will eradicate most infections which may already be present or arise in lesions of the anorectal area.

Indications:
a) For the treatment of internal and external haemorrhoids
b) Haemorrhoids in pregnancy and post-partum
c) Anal pruritus, peri-anal eczema, anal fissures and proctitis
d) Post-haemorrhoidectomy application to relieve pain and discomfort

Contra-indications: Known hyper-sensitivity to any of the ingredients. In pregnant animals administration of corticosteroid can cause abnormalities of foetal development. The relevance of this finding to human beings has not been established. However, topical steroids should not be used extensively in pregnancy, ie in large amounts of for long periods. Hydrocortisone may pass into human breast milk. This product should not be used in pregnancy or lactation unless considered essential by the physician. Topical corticosteroid preparations are contra-indicated in the presence of untreated infections of viral, bacterial, tuberculous, parasitic or fungal origin.

Dosage and direction for use: A suppository is inserted morning and evening and after each stool.

Side effect and special precautions:
Long term continuous treatment with topical corticosteroids should be avoided as far as possible as this may cause atrophic changes in the skin leading to thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasiae,ecchymoses, urticaria and rash. These changes are particularly likely to occur when occlusive dressings are used. In persons sensitive to any of the ingredients of the suppositories, anal irritation may occur.
Systemic absorption of topically applied corticosteroids may occur particularly under the following conditions when large quantities are used or when application is made to wide areas of the body, or to damaged skins, when potent topical corticosteroids area used and when the occlusive dressing technique is applied. Depression of the hypothalamic-pituitary-adrenal axis with consequent suppression of the adrenal gland may occur. These effects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been rarely reported. None of these effects have been reported following the use of Proctosedyl.

Before prescribing the product any potential malignancies should be excluded.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

The following special precaution is recommended:
If a secondary microbial skin infection is present,

Suit able concomitant anti-microbial therapy should be instituted.

Known symptoms of overdosage and particulars of its treatment: Not applicable.

Presentation: Pack of 10 suppositories.

Storage direction: Store at 2 - 8°C

Manufacturer of Suppository:
PT Aventis Pharma, Jakarta, Indonesia

Date of Revision: July 2019