

Abridged Prescribing Information

Cream with Beclomethasone, Phenylephrine & Lignocaine Proctosedyl[®] bd

COMPOSITION:

Beclomethasone Dipropionate IP 0.025% w/w + Phenylephrine Hydrochloride IP 0.1% w/w + Lignocaine Hydrochloride IP 2.5% w/w + Chlorocresol IP (as preservative) 0.1% w/w in aqueous cream base
Pack : 20gm tube with applicator

THERAPEUTIC INDICATIONS :

Proctosedyl bd is indicated for pain and bleeding associated with anal fissures and internal or external haemorrhoids; post haemorrhoidectomy pain; minor degrees of proctitis.

DOSAGE AND ADMINISTRATION: Apply a small amount of cream two or three times a day initially, using the applicator if internal administration is required. When inflammation is subsiding, once-daily application is sufficient in most cases. One tube should provide treatment for at least a week

SAFETY-RELATED INFORMATION

Contraindications: Corticosteroids should not be used in the presence of infection unless effective chemotherapy is also employed. Hypersensitivity to any component of the preparation.

Warnings : *Beclomethasone Dipropionate* - Visual disturbance may be associated 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). In case of systemic absorption : Pheochromocytoma crisis. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Precautions : Topical administration of corticosteroids to pregnant animals 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, i.e. in large amounts or for prolonged periods.

Beclomethasone Dipropionate - In case of systemic absorption : Hypertrophic cardiomyopathy has been reported after systemic administration of glucocorticosteroids in preterm infants. In infants receiving administration of systemic glucocorticosteroids, echocardiograms should be performed to monitor myocardial structure and function.

Pregnancy & Lactation : Use with caution in pregnant or lactating women. Should not be used extensively in pregnant women i.e., in large amounts or for prolonged periods.

Adverse Reactions: Prolonged and intensive treatment with active, corticosteroid preparations may cause local atrophic changes in the skin.

Beclomethasone Dipropionate : Eye disorders : Chorioretinopathy (frequency - not known) ; Blurred vision (frequency - not known). Endocrine disorders: Pheochromocytoma crisis (corticosteroids class effect) (Frequency - not known) (systemic), Cardiac Disorders : Hypertrophic cardiomyopathy in preterm infants (systemic)

Phenylephrine: Cardiac Disorders - Frequency Not Known: Reflex bradycardia, Renal and Urinary disorders - Frequency not known: Urinary retention

For full prescribing information, please contact Sanofi India Ltd, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source: Anovate PI dated 08/16, Phenylephrine GLU Version 1 dated 15 Dec 2015, Glucocorticoids GLU Version 4.1 dated 12th December 2017

Updated: August 2018