

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

This package insert is continually updated: Please read carefully before using a new pack

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

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.

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) (see section Adverse Reactions).

In case of systemic absorption : Pheochromocytoma crisis, which can be fatal, has been reported after administration of corticosteroids. Corticosteroids should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation (see section Adverse Reactions)

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.

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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. (see section Adverse Reactions)

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

As with all topical corticosteroids, if this preparation is used for prolonged periods, the consequence of systemic absorption should be considered, especially in children. 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

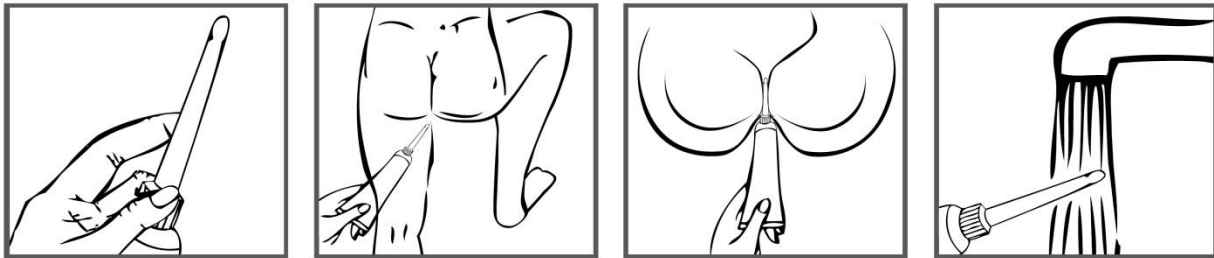
Storage:

Store below 30°C. Keep away from reach of children.

Direction for use:

For external haemorrhoids, use the cream directly.

For internal haemorrhoids, use the applicator as follows :



1. Fix applicator/cannula by rotating clockwise on the nozzle of the tube.
2. Stand with one leg raised on the chair or lie down on left side
3. Remove the cap gently and insert the applicator attached with tube into the anus (passage will be much smoother if applicator is lubricated prior to the insertion)
4. Squeeze the tube to the required amount
5. Slowly remove the tube with the applicator
6. Take applicator apart and wash it thoroughly with soap and warm water and replace the cap

Presentation:

20 gm tube with applicator nozzle

Manufactured by:

Encube Ethicals Pvt Ltd, Plot No C-1, Madkaim Industrial estate, Ponda, Goa. 403 404

Marketed by:

Registered Office : Sanofi India Ltd , Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072.

Ref : Anovate PI dated 08/16, Phenylephrine GLU Version1dated 15 Dec 2015, Glucocorticoids GLU Version 4.1 dated 12th December 2017.

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