

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

Description:

The clinical effectiveness of Proctosedyl® bd is attributable to the marked local anti-inflammatory property of the corticosteroid Beclomethasone Dipropionate, the analgesic effect of lignocaine, and the vasoconstrictor effect of Phenylephrine Hydrochloride.

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.

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.

Adverse Reactions:

As with all topical corticosteroids, if Proctosedyl® bd 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.

Storage:

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

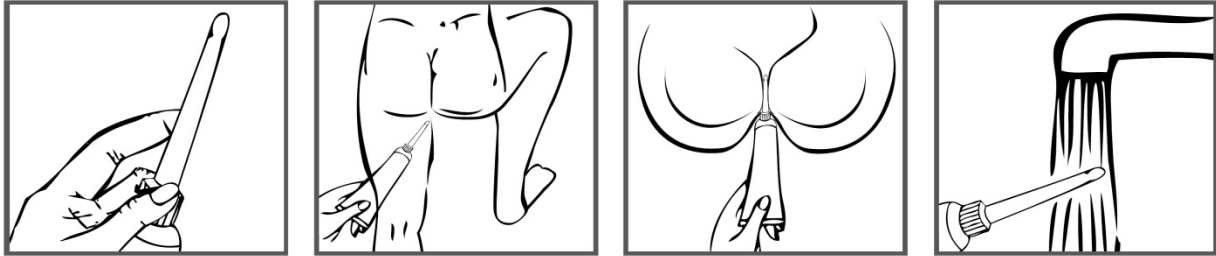
Presentation:

20 gm tube with applicator nozzle

Direction for use:

For external haemorrhoids, use the cream directly.

For internal haemorrhoids, use the applicator as follows:



1. Fix applicator/cannula (by rotating clock-wise) on the nozzle of the tube.
2. Stand with one leg raised on a chair, or lie down on left side.
3. Remove the cap and gently 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 the applicator apart, wash it thoroughly with soap and warm water and replace the cap.

Manufactured by:

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

Marketed by:

Sanofi India Private Limited

Gala no. 5, Ground Floor, Building no. B1, Citylink Warehousing Complex,

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