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BAUSCH Health		
DATE:	2020-08-12	
REVISION:	1 (2020-08-12)	
PRODUCT:	Proctosedyl SG - 15g	
CODE:	20002979A	
COMPONENT:	Insert	
SIZE:	180 x 192 mm	
CUSTOMER/COUNTRY:	Sanofi / Singapore	
OPERATOR:	Singapore	
<hr/>		
PLANT/OPERATOR:	BH Laval / EB	
SPECIFICATION:	Insert 180x192 mm	
DATAMATRIX:	20002979A	
DOCUMENT:	pfb_20002979A	
<hr/>		
COLORS:	TBC - DIELINE	
<hr/>		
CHANGE:	CR2020_1117B: new production at Laval.	
<hr/>		
ELEC. EDITION:	<input type="checkbox"/> □ LEGEND <input type="checkbox"/> □ DIE/SPEC <input type="checkbox"/> □ COLORS	
	<input type="checkbox"/> □ READING <input type="checkbox"/> □ CODES <input type="checkbox"/> □ OUTLINE	
	<input checked="" type="checkbox"/> PFB <input type="checkbox"/> □ PTV <input type="checkbox"/> □ FINAL	
SIGNATURES:		

Proctosedyl®

Hydrocortisone, Dibucaine hydrochloride, Neomycin B Sulfate, Esculin

Ointment



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Trade name: Proctosedyl Ointment

Composition: Each gram of ointment contains the following active ingredients:

Dibucaine hydrochloride	5mg
Hydrocortisone	5mg
Neomycin B sulfate	10mg
Esculin	10mg

Identificaton:

An odourless yellowish-white translucent greasy ointment

Pharmacologic action: The local anesthetic dibucaine hydrochloride prevents or relieves the severe pain sometimes encountered in strangulated haemorrhoids, fissure and perianal hematoma, 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 sulfate, will eradicate most infections which may already be present or arise in lesions of the anorectal area.

Indications:

- For the treatment of internal and external hemorrhoids
- Hemorrhoids in pregnancy and post-partum
- Anal pruritus, peri-anal eczema, anal fissure and proctitis
- Post-haemorrhoidectomy application to relieve pain and discomfort

Contraindications: Known hypersensitivity to any of the ingredients. In pregnant animals administration of corticosteroids 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 or 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 contraindicated in the presence of untreated infections of viral, bacterial, tuberculous, parasitic or fungal origin.

Dosage and direction for use: Apply the ointment in small quantity with the finger on the painful pruritic area morning and evening after each stool. For deep application, attach cannula to tube, insert to full extent and squeeze tube gently from lower end whilst withdrawing. The ointment may be used separately or concurrently with the suppositories.

Side effects 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, contact dermatitis and rash. These changes are particularly likely to occur when occlusive dressings are used. 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 skin, when potent topical corticosteroids are 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 side effects have been reported following the use of Proctosedyl.

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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 (CSR) 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, suitable concomitant anti-microbial therapy should be instituted.

Known symptoms of overdose and particulars of its treatment: Not applicable

Presentation: Tube containing 15g ointment

Storage direction: Ointment: Store below 25°C

Manufacturer: Bausch Health Companies Inc., 2150 Boul. St. Elzéar Ouest, Laval QC H7L 4A8, CANADA

Date of revision: July 2020

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