

## NEW ZEALAND DATA SHEET

### 1 PROCTOSEDYL® (0.5% W/W/0.5 % W/W OINTMENT AND 5 MG/5 MG SUPPOSITORIES)

PROCTOSEDYL 5 mg/5 mg suppository

PROCTOSEDYL 0.5% w/w/0.5% w/w rectal ointment

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository or gram of ointment contains the following active ingredients: cinchocaine hydrochloride BP 5mg, hydrocortisone BP 5mg.

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

PROCTOSEDYL is available as smooth off-white suppositories and as an odourless, yellowish- white, translucent, greasy ointment.

### 4 CLINICAL PARTICULARS

#### 4.1 THERAPEUTIC INDICATIONS

For symptomatic relief of external and internal haemorrhoids, anal pruritus, anal fissure, perianal eczema.

Pre and post-operative treatment of haemorrhoidectomy patients. Post-partum haemorrhoidal conditions.

Non-infective proctitis.

#### 4.2 DOSE AND METHOD OF ADMINISTRATION

## **Dose**

Suppositories or ointment applications: three times daily for first week, after morning stool, noon and evening; twice daily for second week, after morning stool and evening; and once daily for third week after morning stool. Except on medical advice, duration of treatment should, as far as possible, not exceed three weeks.

## **Method of administration**

Suppositories:

Insert one suppository in the rectum.

Ointment:

15g and 30g tubes: apply a small quantity of ointment (only that necessary to cover the affected area), with the finger, to the painful or pruritic area. For deeper application, attach cannula, gently insert the cannula in the rectum and squeeze tube from the lower end whilst withdrawing. However, for very inflamed and painful lesions, it is advisable initially to apply the ointment internally with the finger, rather than insert the cannula.

## **4.3 CONTRAINDICATIONS**

Hypersensitivity to hydrocortisone or cinchocaine or any of the excipients in PROCTOSEDYL (see section 6.1).

Children 12 years of age and under.

All steroid preparations are contraindicated in uncontrolled infections, bacterial, viral (eg. herpes simplex, herpes zoster and vaccinia), fungal, or parasitic infections and when infective pathologies of sexually transmissible diseases occur in the area to be treated.

In tuberculosis the use of steroids may exacerbate the disease process.

## **4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

Hydrocortisone can cause thinning and damage to the skin.

As with all preparations containing topical corticosteroids, the possibility of systemic absorption should be considered. Hydrocortisone is systemically bio-available from suppositories applied to the rectum. Absorption of hydrocortisone may be increased across abraded or inflamed surfaces. Adrenal suppression can occur even without occlusion. (See section 4.8).

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).

Pheochromocytoma crisis, which can be fatal, has been reported after administration of corticosteroids. In patients with suspected or identified pheochromocytoma, corticosteroids should only be administered after an appropriate risk/benefit evaluation (See section 4.8).

Hypertrophic cardiomyopathy has been reported after systemic administration of hydrocortisone in preterm infants. In infants receiving hydrocortisone, echocardiograms should be performed to monitor myocardial structure and function. (See section 4.8).

Long-term continuous therapy should be avoided. Except on medical advice, the maximum duration of therapy with these products should not exceed that recommended (see section 4.2). Discontinue use if sensitisation occurs. Specific measures against infections, allergy and other causal factors must not be neglected.

#### **4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION**

Nil known.

No interaction studies have been performed.

#### **4.6 FERTILITY, PREGNANCY AND LACTATION**

##### **Pregnancy**

Category A.

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, i.e. in large amounts or for long periods

##### **Breast-feeding**

Hydrocortisone may pass into human breast milk. Given the possible maternal systemic absorption and lack of data, PROCTOSEDYL should preferably not be used during lactation.

#### **4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

Not relevant.

#### **4.8 UNDESIRABLE EFFECTS**

PROCTOSEDYL is generally well tolerated. Certain patients may experience burning upon application, especially if the mucous membrane is not intact.

Urticaria has been reported.

##### **For suppository only:**

In persons sensitive to any of the ingredients of the suppositories, anal irritation may occur.

##### **Applies to topical and systemic hydrocortisone:**

Endocrine disorders:

Not known: Adrenal suppression.

When applied topically and to a large enough area, especially of damaged skin for long enough, or if under occlusive dressing, hydrocortisone may have this adverse effect.

Eye disorders:

Not known: Chorioretinopathy (See PRECAUTIONS), blurred vision

Skin and subcutaneous disorders:

Not known: Urticaria, Rash.

##### **Applies to systemic hydrocortisone:**

Endocrine disorders:

Not known: Pheochromocytoma crisis (corticosteroids class effect) (See section 4.4).

Cardiac disorders:

Not known: Hypertrophic cardiomyopathy in preterm infants (See section 4.4).

##### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

#### **4.9 OVERDOSE**

Overdosage has not been reported.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 PHARMACODYNAMIC PROPERTIES**

Pharmacotherapeutic group: Glucocorticoids, ATC code: H02AB09

The rationale of the combination is to combine the local anaesthetic, analgesic and spasmolytic effect of cinchocaine with the antipruritic and anti-inflammatory action of hydrocortisone. These ingredients are presented in emollient vehicles.

Cinchocaine hydrochloride is a potent local anaesthetic agent. It is recognised as being one of the longest acting of those agents commonly employed. It is included in PROCTOSEDYL for the relief of pain and spasm.

Topical corticosteroids have anti-inflammatory, anti-pruritic and vasoconstrictive actions. Hydrocortisone is a low potency glucocorticoid which is safe and effective as a topical anti-inflammatory drug in the concentration employed in PROCTOSEDYL.

### **5.2 PHARMACOKINETIC PROPERTIES**

No pharmacokinetic data are available by any route of administration.

### **5.3 PRECLINICAL SAFETY DATA**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 LIST OF EXCIPIENTS**

PROCTOSEDYL Suppositories:

- Hard fat

PROCTOSEDYL Ointment:

- Lanolin
- Liquid paraffin
- White soft paraffin

## **6.2 INCOMPATIBILITIES**

It is not known if PROCTOSEDYL Ointment or Suppositories adversely affects latex rubber condoms. Thus it is recommended that you avoid contact between latex rubber condoms and PROCTOSEDYL Ointment or Suppositories.

## **6.3 SHELF LIFE**

PROCTOSEDYL Suppositories: 18 months

PROCTOSEDYL Ointment: 36 months

## **6.4 SPECIAL PRECAUTIONS FOR STORAGE**

PROCTOSEDYL Suppositories: Store at 2-8°C. Refrigerate. Do not freeze.

PROCTOSEDYL Ointment: Store below 30°C. Protect from light.

## **6.5 NATURE AND CONTENTS OF CONTAINER AND SPECIAL EQUIPMENT FOR USE, ADMINISTRATION OR IMPLANTATION**

PROCTOSEDYL Suppositories: Blister pack of 12 suppositories

PROCTOSEDYL Ointment: 15g and 30g aluminium tube with cannula

Not all pack sizes may be marketed.

## **6.6 SPECIAL PRECAUTIONS FOR DISPOSAL**

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

## **7 MEDICINE SCHEDULE**

Pharmacy Only Medicine

## **8 SPONSOR**

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## **9 DATE OF FIRST APPROVAL**

31 December 1969

## **10 DATE OF REVISION OF THE TEXT**

11 January 2018

Summary of changes:

<b>Section changed</b>	<b>Summary of new information</b>
All	Medsafe format change
4.3	Addition of hypersensitivity to excipients, and infections
4.4	Addition of precautions on skin thinning, adrenal suppression, chorioretinopathy and hypertrophic cardiomyopathy
4.6	Addition of breast-feeding information
4.8	Addition of adverse effects
5.1	Addition of Pharmacodynamic properties
4.4	Amendment to Precautions to state that visual disturbance may be associated with systemic and topical corticosteroid use
4.8	Amendment to the Adverse Events to state that visual disturbance may be associated with systemic and topical corticosteroid use