AUSTRALIAN PRODUCT INFORMATION – PROCTOSEDYL OINTMENT AND SUPPOSITORIES (CINCHOCAINE HYDROCHLORIDE, HYDROCORTISONE)

1 NAME OF THE MEDICINE

cinchocaine hydrochloride, hydrocortisone

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains cinchocaine hydrochloride BP 5mg and hydrocortisone BP 5mg.

Each gram of ointment contains cinchocaine hydrochloride BP 5mg and hydrocortisone BP 5mg.

3 PHARMACEUTICAL FORM

Proctosedyl is supplied as smooth, off-white suppositories or 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. Pre and post-operative treatment of haemorrhoidectomy patients.

Post-partum haemorrhoidal conditions. Non-infective proctitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

Suppository or ointment applications: Three times daily for first week, after morning stool, noon and evening. PROCTOSEDYL should not be used for longer than 7 days unless prescribed by a doctor.

If a longer period of treatment is required, the following dosage regime should be implemented. This length of treatment should only occur upon medical advice:

Twice daily for second week, after morning stool and evening; and once daily for third week after morning stool. Duration of treatment should, as far as possible, not exceed three weeks.

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 in the rectum to full extent and squeeze tube from the lower end whilst withdrawing.

4.3 CONTRAINDICATIONS

Hypersensitivity to hydrocortisone or cinchocaine or any of the excipients (see Section 2 Qualitative and Quantitative Composition). 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

Identified precautions

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 bioavailable 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 Adverse effects [Undesirable Effects]).

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 Adverse effects [Undesirable Effects]).

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 Adverse effects [Undesirable Effects]).

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 Dosage and Method of Administration). If treatment is required beyond seven days, the patient should be advised to consult a physician for assessment of the condition. This may include a proctological examination. Discontinue use if sensitisation occurs. Specific measures against infections, allergy and other causal factors must not be neglected.

Use in the elderly

No data available.

Paediatric use

PROCTOSEDYL is not recommended for use in children under 12 years of age.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No interactions with other medicines have been identified.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy – 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.

Use in lactation.

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

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Certain patients may experience:

- Burning upon application, especially if the mucous membrane is not intact.
- Eye disorder
- 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 Section 4.4 Special Warnings and Precautions for Use), 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 Special warnings and precautions for use).

Cardiac disorders:

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

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Overdosage has not been reported.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

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 with anti-pyretic properties resulting from its inhibition of the transmission of nerve impulses. 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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Suppositories inactive ingredient is hard fat.

Ointment inactive ingredients are white soft paraffin, liquid paraffin and wool fat.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Suppositories:

Store at 2°C to 8 °C. Refrigerate. Do not freeze. Protect from light.

Ointment (with cannula):

Store below 25°C. Protect from light.

6.5 NATURE AND CONTENTS OF CONTAINER

Suppositories:

Strip pack of 12

Ointment (with cannula):

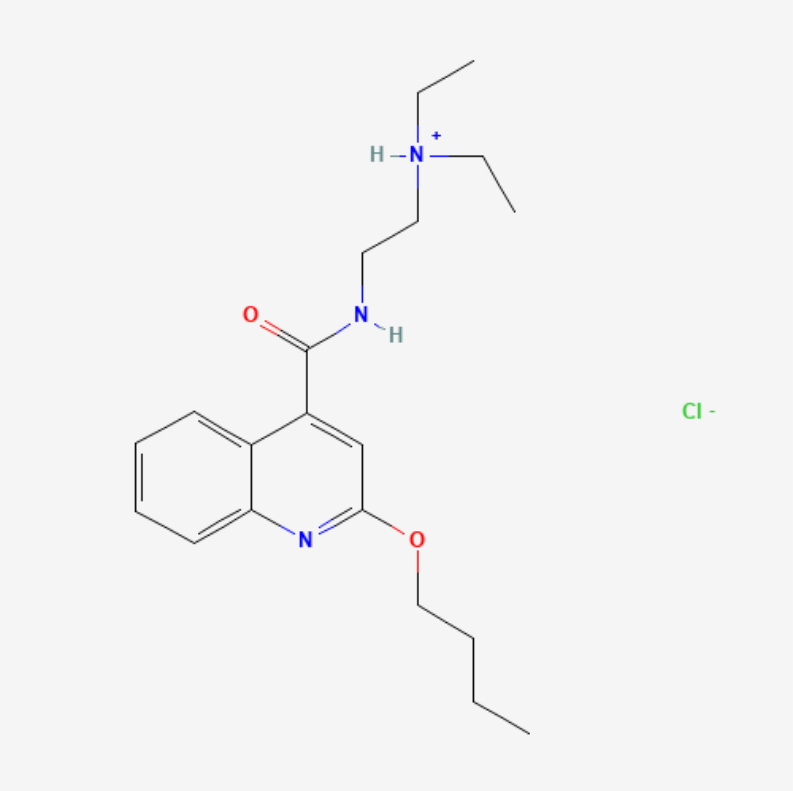
15g and 30g tubes.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

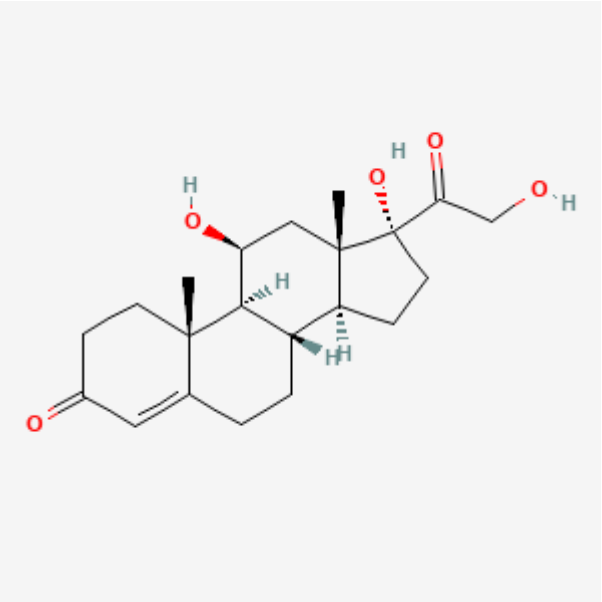
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



Cinchocaine Hydrochloride



Hydrocortisone

CAS number

Cinchocaine hydrochloride:

61-12-1

Hydrocortisone:

50-23-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Pharmacy Medicine (Schedule 2)

8 SPONSOR

Sanofi Consumer Healthcare

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9 DATE OF FIRST APPROVAL

26 June 1992

10 DATE OF REVISION

27 May 2022

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
ALL	PI reformat