PRODUCT INFORMATION
PROCTOSEDYL OINTMENT AND SUPPOSITORIES

NAME OF DRUG

PROCTOSEDYL (cinchocaine hydrochloride, hydrocortisone)

DESCRIPTION

PROCTOSEDYL is supplied as suppositories or as an odourless yellowish-white translucent greasy ointment.

Each suppository contains cinchocaine hydrochloride BP 5mg, hydrocortisone BP 5mg and the excipient hard fat.

Each gram of ointment contains cinchocaine hydrochloride BP 5mg, hydrocortisone BP 5mg and the excipients white soft paraffin, liquid paraffin and wool fat.

PHARMACOLOGY

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.

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.

CONTRAINDICATIONS

Hypersensitivity to hydrocortisone or cinchocaine or any of the excipients (see DESCRIPTION). 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.

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 ADVERSE EFFECTS).

Systemic glucocorticoid treatment can cause chorioretinopathy which can lead to visual disorders including visual loss. Prolonged use of systemic glucocorticoid treatment even at low dose can cause chorioretinopathy (See ADVERSE EFFECTS).

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 ADVERSE 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 ADVERSE 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 DOSAGE AND 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 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.

PAEDIATRIC USE

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

INTERACTIONS WITH OTHER MEDICINES

No interactions with other medicines have been identified.

ADVERSE 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.

Skin and subcutaneous disorders:

Not known: Urticaria, Rash.

Applies to systemic hydrocortisone:

Endocrine disorders:

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

Eye disorders:

Not known: Chorioretinopathy (See PRECAUTIONS).

Cardiac disorders:

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

DOSAGE AND 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.

OVERDOSAGE

Overdosage has not been reported.

PRESENTATION AND STORAGE CONDITIONS

Suppositories:

Strip pack of 12

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

Ointment (with cannula):

15g and 30g tubes.

Store below 25°C. Protect from light.

NAME AND ADDRESS OF THE SPONSOR

sanofi-aventis australia pty ltd

12-24 Talavera Road,

Macquarie Park, NSW 2113

POISON SCHEDULE OF THE MEDICINE

Schedule 2

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

26 June 1992

DATE OF MOST RECENT AMENDMENT

04 September 2017