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 or gram of ointment contains cinchocaine hydrochloride BP 5mg, hydrocortisone BP 5mg.

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. All steroid preparations are contraindicated in uncontrolled infections, viral infections (eg. herpes simplex, herpes zoster and vaccinia), and when infective pathologies of sexually transmissible diseases occur in the area to be treated. When fungal infection is present additional therapy with a topical antymycotic should be instituted. In tuberculosis the use of steroids may exacerbate the disease process.

PRECAUTIONS
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.
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.

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.
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.

PRESENTATION

Suppositories: 12's (Schedule 2)
Ointment (with cannula): 15g, 30g (Schedule 2)

STORAGE CONDITIONS

Suppositories: Store at 2°C to 8 °C. Refrigerate. Do not freeze. Protect from light.
Ointment 15g, 30g: Store below 25°C. Protect from light.

DISTRIBUTOR

sanofi-aventis australia pty ltd
12-24 Talavera Road,
Macquarie Park, NSW 2113

Approved by the Therapeutic Goods Administration (TGA): 21st May 2007