

# Data Sheet

## Proctosedyl® Ointment and Suppositories

### Name of Medicine

Cinchocaine hydrochloride BP 5mg/g ointment or suppository  
Hydrocortisone BP 5mg/g ointment or suppository

### Presentation

PROCTOSEDYL is available as smooth off-white suppositories and as an odourless, yellowish-white, translucent, greasy ointment. Each suppository or gram of ointment contains the following active ingredients: cinchocaine hydrochloride BP 5mg, hydrocortisone BP 5mg.

### Uses

#### Actions

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.

#### 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.

#### Dosage and Administration

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.

##### 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.

#### Contraindications

Hypersensitivity to hydrocortisone or cinchocaine.

Children 12 years of age and under.

All steroid preparations are contraindicated in uncontrolled infections, viral infections, (e.g. 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 topical antimycotic should be instituted. In tuberculosis the use of steroids may exacerbate the disease process.

### **Warnings and Precautions**

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. 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). Discontinue use if sensitisation occurs. Specific measures against infections, allergy and other causal factors must not be neglected

### **Pregnancy and Lactation**

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

### **Adverse Effects**

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

### **Interactions**

Nil known.

### **Overdosage**

Overdosage has not been reported.

### **Pharmaceutical Precautions**

#### **Special Precautions for Storage**

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

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

### **Medicine Classification**

Pharmacy Only Medicine

### **Package Quantities**

PROCTOSEDYL Suppositories: 12's

PROCTOSEDYL Ointment: 15g and 30g with cannula

### **Further Information**

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.

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