SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Proctosedyl Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cichocaine Hydrochloride (Micro) BP 0.5 %ww, Hydrocortisone (Micro) EP 0.5 %ww

3. PHARMACEUTICAL FORM

Yellowish-white translucent greasy ointment.

CLINICAL PARTICULARS

4.1 Therapeutic indications

The local anaesthetic cinchocaine relieves pain and relaxes sphincteric spasm. Pruritis and inflammation are relieved by hydrocortisone, which also decreases serious discharge.

Proctosedyl is, therefore, useful for the short term relief (not more than 7 days) of pain, irritation and pruritis associated with haemorrhoids and pruritis ani.

4.2 Posology and method of administration

Apply the ointment in small quantities with the finger, on the painful or pruritic area, morning and evening and after each stool. For deep application attach cannula to tube, insert to full extent and squeeze tube gently from lower end whilst withdrawing.

The ointment may be used separately or concurrently with the suppositories.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

Not for use in the presence of infections.

4.4 Special warnings and precautions for use

Apply only to the region of the rectum and anus and surrounding skin. Hydrocortisone can cause thinning and damage to the skin especially of the face.

As with all preparations containing topical steroids, the possibility of systemic absorption should be considered. In particular, long-term continuous therapy should be avoided in infants. Adrenal suppression can occur even without occlusion.

4.5 Interactions with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

In persons sensitive to any of the ingredients, skin rash may occur. Although less likely to cause adrenal suppression when applied topically, Hydrocortisone, applied to a large enough area, especially of damaged skin for long enough, or if under occlusive dressing, may have this adverse effect.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cinchocaine is a local anaesthetic of the amide type.

Hydrocortisone is a glucocorticoid with anti-inflammatory and other properties.

5.2 Pharmacokinetic properties

The literature states that absorption of hydrocortisone does occur through the skin, particularly denuded skin. However, this absorption is not of a clinical significance as hydrocortisone topically, has only rarely been associated with side effects resulting from pituitary adrenal suppression.

Cinchocaine is little absorbed through the intact skin, but absorbed through mucous membranes. Like other local anaesthetics of the amide type, cinchocaine is metabolised in the liver.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wool fat, liquid paraffin, white soft paraffin.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium tube with plastic cannula (30g tubes).

6.6 Instructions for use/handling

None stated.

7. MARKETING AUTHORISATION HOLDER

sanofi-aventis
One Onslow Street
Guildford
Surrey
GU1 4YS

8. MARKETING AUTHORISATION NUMBER

PL 04425/0207

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 July 2005

10. DATE OF (PARTIAL) REVISION OF TEXT

Decemebr 2006

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