

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Proctosedyl Suppositories

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each suppository contains 5mg of Hydrocortisone, 5mg of Cinchocaine Hydrochloride, 10mg of Aesculin and 10mg of Framycetin Sulphate

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Suppositories

Off-white, torpedo shaped, homogenous suppositories.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

In the local management of pain, pruritus and inflammation associated with internal or external haemorrhoids, and such haemorrhoidal complications as fissures, proctitis, perianal eczema, and post-operative states.

### 4.2 Posology and method of administration

Dosage:

Application to external surface or by means of the cannula into the rectum, twice daily and after each bowel movement. Treatment should last for a week.

Administration

Topical, Intrarectal and perianal

### 4.3 Contraindications

1. Use in the presence of untreated infections of viral, tuberculous or fungal origin.
2. Use in patients hypersensitive to the active ingredients or any of the excipients.

### 4.4 Special warnings and precautions for use

1. Continuous treatment for longer than three weeks should be avoided in patients under the age of three years because of the possibility of adrenocortical suppression and growth retardation.
2. Continuous application without interruption will result in local atrophy of the skin, striate, and superficial vascular dilation.
3. Prolonged use of an anti-infective may result in the development of super-infection due to organisms, including fungi, resistant to that anti-infective.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None stated.

#### **4.6 Fertility, pregnancy and lactation**

Animal studies have shown teratogenic effects. To date similar effects have not been shown to occur in man. This product should not be used in pregnancy or lactation unless considered essential by the physician

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

Itching, pain or rash may develop around the back passage.

#### **4.9 Overdose**

In the rare event of overdosage, supportive and symptomatic therapy is indicated.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ATC code: CO5A

A combination of a glucocorticoid, local anaesthetic and antibacterial.

#### **5.2 Pharmacokinetic properties**

None Stated.

#### **5.3 Preclinical safety data**

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Suppocire AM. (Hard fat)

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf life**

18 Months.

#### **6.4 Special precautions for storage**

Store at 2°C to 8°C.

## **6.5 Nature and contents of container**

Each suppository is contained within a pocket formed from a PVC/PE plastic strip. There are 12 suppositories per pack.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Sanofi-Aventis Ireland Ltd. T/A SANOFI  
Citywest Business Campus  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA 540/62/2

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1978

Date of last renewal: 25<sup>th</sup> November 2009

## **10 DATE OF REVISION OF THE TEXT**

July 2012