Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anugesic HC Suppositories

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.8 g suppository contains:

Pramocaine Hydrochloride	27	mg
Hydrocortisone Acetate	5	mg
Benzyl Benzoate	33	mg
Bismuth oxide	24	mg
Balsam Peru	49	mg
Zinc Oxide	296	mg
Bismuth Subgallate	59	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suppository
The product is a buff coloured suppository.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Anugesic HC Suppositories are indicated for the comprehensive symptomatic treatment of severe and acute discomfort or pain associated with internal and external haemorrhoids, proctitis, cryptitis, anal fissures, pruritus ani and perianal sinuses. Also indicated post-operatively in ano-rectal surgical procedures.

4.2 Posology and method of administration

Intrarectal.

Adults: Remove plastic cover and insert one suppository into the anus at night, in the morning and after each evacuation.

Not to be taken orally.

Elderly (over 65 years): As for adults.

Children: Not recommended.

4.3 Contraindications

Tubercular, fungal and viral lesions including herpes simplex, vaccinia and varicella.
History of sensitivity to any of the constituents.

4.4 Special warnings and precautions for use

As with all products containing topical steroids the possibility of systemic absorption should be borne in mind.

Prolonged or excessive use may produce systemic corticosteroid effects, and use for periods longer than seven days is not recommended.

Following symptomatic relief definitive diagnosis should be established.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Should not be used during pregnancy or lactation unless considered essential by the physician.

There is inadequate evidence of safety in human pregnancy and there may be a very small risk of cleft palate and intra-uterine growth retardation as well as suppression of the neonatal hypothalamic pituitary-adrenal (HPA) axis. There is evidence of harmful effects in animals.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely, sensitivity reactions. Patients may occasionally experience transient burning on application, especially if the anoderm is not intact.

4.9 Overdose

If swallowed, fever, nausea, vomiting, stomach cramps and diarrhoea may develop 3-12 hours after ingestion.

Pramocaine is relatively non-toxic and less sensitising than other local anaesthetics.

Hydrocortisone does not normally produce toxic effects in an acute single overdose.

Treatment of a large acute overdosage should include gastric lavage, purgation with magnesium sulphate and complete bed rest. If necessary, give oxygen and general supportive measures.

Methaemoglobinaemia should be treated by intravenous methylthioninium chloride.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pramocaine hydrochloride is a surface anaesthetic used on the skin and mucous membranes to relieve surface pain and pruritus.

Hydrocortisone acetate has the general properties of hydrocortisone and the anti-inflammatory action is of primary interest in this product.

Benzyl benzoate is used as a solubilising agent and has mild antiseptic and preservative properties.

Bismuth oxide exerts a protective action on mucous membranes and raw surfaces. It is weakly astringent and is reported to have antiseptic properties.

Balsam Peru has protective properties and a very mild antiseptic action by virtue of its content of cinnamic and benzoic acids. It is believed to promote the growth of epithelial cells, zinc oxide acts as an astringent and mild antiseptic.

5.2 Pharmacokinetic properties

It is well known that topically applied corticosteroids can be absorbed percutaneously. This appears to be more likely upon repeated or prolonged use. The remaining active ingredients in Anugesic HC Suppositories exert their therapeutic effect without being absorbed into the systemic circulation. These observations are supported by evidence from various studies and reviews.

5.3 Preclinical safety data

Preclinical data does not add anything of further significance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Hydrogen Phosphate
Hard Fat A
Hard Fat C
Theobroma Oil

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

Printed strip pack consisting of white opaque pvc/polythene laminated film. There are six suppositories in a strip and two strips (12 suppositories) in a box.

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

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA 822/9/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 15 March 2010

10 DATE OF REVISION OF THE TEXT

June 2011