Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Anugesic HC Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100g of cream contains:

Zinc oxide	12.35g
Balsam peru	1.85g
Benzyl benzoate	1.2g
Pramocaine hydrochloride	1.0g
Bismuth oxide	0.875g
Hydrocortisone acetate	0.5g

Excipients with known effect:
Propyl parahydroxybenzoate (E216) 0.01g
Methyl parahydroxybenzoate (E218) 0.11g
Propylene Glycol 8.0g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A smooth, homogeneous buff coloured cream with the characteristic odour of balsam peru.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Anugesic HC Cream is 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. It is also indicated post-operatively in ano-rectal surgical procedures.

4.2 Posology and method of administration

Posology

Adults:

Apply cream to the affected area at night, in the morning and after each evacuation. Thoroughly cleanse the affected area, dry and apply cream by gently smoothing onto the affected area. For internal conditions use rectal nozzle provided and clean it after each use.

Not to be taken orally.

Elderly (over 65 years):

As for adults.

Paediatric population:

Not recommended.

Method of administration
For topical use only.

4.3 Contraindications

Tubercular, fungal and viral lesions including herpes simplex, vaccinia and varicella.

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

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.

Prolonged use of uninterrupted occlusions or use with extensive occlusive dressings may enhance systemic absorption.
Continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation.
Contains propylene glycol which may cause skin irritation.
Contains E216 and E218 which may cause allergic reactions (possibly delayed).

Following symptomatic relief definitive diagnosis should be established.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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 HPA axis. There is evidence of harmful effects in animals.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

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 sulfate 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

Pharmacotherapeutic Group; Antihemorrhoidals for topical use,
ATC code: C05A A01.

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 solubilizing 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 Cream 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

Liquid paraffin
Glyceryl monostearate
Propylene glycol (E1520)
Polysorbate 60
Sorbitan Stearate
Titanium dioxide (E171)
Methyl parahydroxbenzoate (E218)
Propyl parahydroxybenzoate (E216)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

Store in the original packaging.

6.5 Nature and contents of container

Externally printed and internally lacquered aluminium tube, with plastic screw cap, of 15, 25, and 30g cream.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0822/009/001

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

October 2016