Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Difflam Spray, 0.15% w/v, Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each puff (175 microlitres) contains 262.5 micrograms of benzydamine hydrochloride (0.15% w/v).
Excipient(s) : includes methyl parahydroxybenzoate (E218) and ethanol
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal spray
Product imported from the UK
Difflam spray is a metered dose spray containing a clear, colourless oromucosal spray solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the symptomatic relief of painful inflammatory conditions of the throat and mouth.

4.2 Posology and method of administration

For <u>oromucosal</u> administration.

<u>ADULTS AND ELDERLY</u>: 4 to 8 puffs, 1½-3 hourly.

<u>CHILDREN (6-12):</u> 4 puffs, 1½-3 hourly.

<u>CHILDREN UNDER 6</u>: One puff to be administered per 4 kg body weight, up to a maximum of 4 puffs, 1½-3 hourly.

Because of the small amount of drug applied, elderly patients can receive the same dose as adults.

The spray should be directed onto the affected area. Uninterrupted treatment should not exceed seven days, except under medical supervision.

4.3 Contraindications

Use in patient with a known hypersensitivity (eg bronchospasm, rhinitis, urticaria) to this product.

4.4 Special warnings and precautions for use

Avoid contact with the eyes.
If the condition is aggravated or not improved use should cease.

Contains methyl parahydroxybenzoate (E218). May cause allergic reactions (possibly delayed).
This medicinal product contains small amounts of ethanol (alcohol) less than 100mg per dose.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Difflam Spray should not be used in pregnancy or lactation unless considered essential by the physician. There is no evidence of a teratogenic effect in animal studies.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Benzydamine is well tolerated; side-effects are minor. Occasionally, oral tissue numbness or 'stinging' sensations may occur. The stinging has been reported to disappear upon continuation of the treatment, however if it persists it is recommended that treatment be discontinued. Hypersensitivity reactions occur very rarely but may be associated with pruritus rash, urticaria, photodermatitis and occasionally laryngospasm or bronchospasm.

In rare cases anaphylactic reactions may occur which can be potentially life-threatening.

4.9 Overdose

Difflam is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. No special measures are required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzydamine exerts an anti-inflammatory and analgesic action by stabilising the cellular membrane and inhibiting prostaglandin synthesis.

5.2 Pharmacokinetic properties

Following oral administration, Benzydamine is rapidly absorbed from the gastrointestinal tract and maximum plasma levels reached after 2-4 hours.
About half of the Benzydamine is excreted unchanged via the kidney at a rate of 10% of the dose within the first 24 hours. The remainder is metabolised, mostly to N-Oxide.

5.3 Preclinical safety data

Non-Clinical Data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated toxicity, genotoxicity, cardiogenic potential, and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Glycerol
Saccharin
Sodium hydrogen carbonate

Ethanol
Methyl parahydroxybenzoate
Mouthwash flavour 52 503/T Firmenich
Polysorbate 20

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer package of the product as marketed in the country of origin

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate or freeze
Store in the original package

6.5 Nature and contents of container

Difflam spray is presented in an overlabelled box containing a 30 ml HDPE bottle with a 170 microlitre metering valve spray pump.

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

Keep the bottle upright during use and when stored
After use the nozzle should be wiped with a tissue to prevent blockage

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd
Unit 10
Ashbourne Business Park
Rath
Ashbourne
County Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/228/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th May 2011

10 DATE OF REVISION OF THE TEXT