Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Locabiotal Pressurised 125 micrograms, Nasal/Oromucosal spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each puff (delivered dose, ex actuator) contains 125micrograms of fusafungine.
The concentration of the solution is 500mg of fusafungine for 100ml.
For full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Nasal/Oromucosal spray solution .
Yellow solution with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of local infections of the nasal passages and oropharynx due to micro-organisms sensitive to this anti-infective.

4.2 Posology and method of administration

Posology
Adults
4 puffs in the mouth and 2 puffs in each nostril 4 times daily.

Special populations
Elderly population
There is no dose adjustment necessary for elderly patients

Renal impairment
There is no dose adjustment necessary for patients suffering from renal impairment

Hepatic impairment
There is no dose adjustment necessary for patients suffering from hepatic impairment

Paediatric population
Locabiotal should not be used in children aged 0 to 30 months because of safety concerns (see section 4.3).

Children over 30 months : 2 puffs in the mouth and (or) 1 puff in each nostril 4 times daily.

Method of administration
Via the mouth and the nose using the appropriate attachment.
Before the very first use, press 4 times on the main actuator so as to prime the valve. The bottle must be held upright between the thumb and index finger with the actuator uppermost. To administer the drug, place the mouth adaptor (white) in the mouth, closing the lips around it. Then press firmly and at length on the adaptor while breathing normally. Use the same procedure for nasal administration, after fitting the nasal adaptor (yellow for adults or transparent for children) on the bottle.

Duration of treatment: Treatment should normally last 7 days. However, if there is no improvement after 7 days, fusafungine should be stopped and medical advice sought.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Children under 30 months (risk of laryngospasm).

4.4 Special warnings and precautions for use

Use with cautions in patients with allergic tendencies and bronchospasm (see section 4.8).
Prolonged use of an anti-infective may result in the development of superinfection due to organisms resistant to the anti-infective.
If symptoms and signs do not improve in one week, alternative therapy should be considered.
Propylene glycol may cause skin irritation.
This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
For Locabiotal, no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3). Cautions should be exercised when prescribing to pregnant women.

Breast-feeding
It is unknown whether Fusafungine is excreted in human breast milk. The excretion of Fusafungine in milk has not been studied in animals. A decision must be made whether to continue/discontinue breast-feeding or to continue/discontinue therapy taking into account the benefit of breast-feeding to the child and the benefit of therapy to the woman. In the absence of data on the excretion of fusafungine into the milk, the treatment is not recommended in breast-feeding women.

Fertility
Studies in animals have shown no effect on fertility in males and females rats (see section 5.3).

4.7 Effects on ability to drive and use machines

Fusafungine has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

The following adverse effects have been observed during treatment with Locabiotal and ranked under the following frequency:

Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000); very rare (<1/10000), not known (cannot be estimated form the available data).

Allergic reactions are very rare but may occur, particularly in patients with allergic tendencies. The most commonly reported undesirable effects are local reactions at the site of application.

General disorders and administration site condition:
Very common: sneezing, dysgueusia, conjunctival congestion.
Common: nose dryness, dry throat, throat irritation, cough, nausea
Not known: vomiting
These do not usually necessitate discontinuation of treatment.

Immune system disorders:
Very rare: anaphylactic shock.

Respiratory, thoracic and mediastinal disorders:
Very rare: asthma, bronchospasm, dyspnoea, laryngeal oedema, laryngospasm.

Skin and subcutaneous tissue disorders:
Very rare: rash, pruritus, urticaria, Quincke's oedema.

In case of allergic reaction, fusafungine should not be readministered.

Due to the risk of anaphylactic shock, in case of respiratory, laryngeal or cutaneous (pruritus, generalised erythema) signs, an intramuscular injection of adrenaline (epinephrine) may be necessary urgently.
The adrenaline usual dose is 0.01 mg/kg by intramuscular route. The dose may be repeated after 15 to 20 minutes if needed.

Please consult local treatment guidelines/protocols for anaphylaxis treatment.

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

There is limited experience with fusafungine overdose. Experience with fusafungine has indicated that circulatory disorders, numbness in mouth, dizziness, worsening of sore and chemical burn of the throat have been reported. Management of overdose should consist of treatment of clinical symptoms and routine monitoring.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Respiratory System, Throat preparations/ Antibiotics, ATC code: R02A B03

Fusafungine is a topical antibiotic produced by Fusanium Luteritium strain 347, with anti-inflammatory properties. It is bacteriostatic.

5.2 Pharmacokinetic properties

The deposition of LOCABIOTAL® is mainly oropharyngeal and nasal. Transient and very low amount of fusafungine may be detected in plasma (limit of quantification of 1 ng/ml) without any consequences on the safety of the product.

5.3 Preclinical safety data

Preclinical safety test including toxicity and embryotoxicity, as well as assay of genotoxic potential revealed no findings of relevance to the prescribing clinician.
Repeated oral fusafungine administration studies in rats showed no effect on the reproductive organs following macroscopic and histological evaluation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aromatic flavour 14868
Ethanol anhydrous
Saccharin
Isopropyl myristate
Norflurane

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not expose to temperature higher than 50°C.
The canister contains a pressurised liquid. Do not pierce the canister.

6.5 Nature and contents of container

Pressurised aluminium canister with a crimp-sealed 25 microlitres metering valve, containing 10 ml of solution corresponding to 400 puffs. The canister is coated with an epoxyphenol resin. One actuator and three adaptors in polyethylene: one mouth adaptor (white), two nasal adaptors (yellow for adults or transparent for children).

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA0068/015/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last Renewal: 13th October 2011

10 DATE OF REVISION OF THE TEXT

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