Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

LOCABIOTAL 500 micrograms per metered dose, Nasal/Oromucosal spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fusafungine 1% w/v
Each metered dose delivers approximately 500 micrograms of fusafungine.

Excipients: trace amounts of ethanol (alcohol) and propylene glycol (E1520).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal/Oromucosal spray solution.
The solution is oily, colourless to pale yellow, clear, 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. Fusafungine is indicated in adults and adolescents (≥ 12 years old).

4.2 Posology and method of administration

Posology

1 spray actuation by mouth and (or) 1 spray actuation in each nostril every 4 hours.
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 12 years because of safety concerns (see section 4.3).

Method of administration
Via the mouth and the nose using the appropriate attachment.
Before the very first use, press 5 times on the main adapter so as to prime the pump. The bottle must be held upright between the thumb and index finger with the adapter uppermost.
To administer the drug, place the mouth adapter (white) in the mouth, closing the lips around it. Then press firmly and at length on the adapter while breathing normally.
Use the same procedure for nasal administration, after fitting the nasal adapter (yellow) 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 any of the excipients listed in section 6.1.
Children under 12 years (see section 4.8).
Patients with allergic tendencies and bronchospasm (see section 4.8).

4.4 Special warnings and precautions for use

In case of allergic reaction, LOCABIOTAL should be stopped and not be readministered (see section 4.8).

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 0.01mg/kg by intramuscular route. The dose may be repeated after 15 to 20 minutes if needed.

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

There have been no documented reports of any interactions with fusafungine used topically.

No interaction 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). Caution 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

Summary of the safety profile
Allergic reactions are very rare but may occur, particularly in patients with allergic tendencies. Severe allergic reactions have also been observed in children (see section 4.3 and 4.4).
The most commonly reported undesirable effects are local reactions at the site of application.

Tabulated list of adverse reactions
The following undesirable effects have been observed during treatment with fusafungine and ranked under the following frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10000 to <1/1000); very rare (≥1/10000); not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse reaction
Immune system disorders	Very rare	Anaphylactic shock
Nervous system disorders	Very common	Dysgeusia
Eye disorders	Very common	Conjunctival congestion
Respiratory, thoracic and mediastinal disorders	Very common	Sneezing
	Common	Nose dryness
		Dry throat
		Throat irritation
		Cough
	Very rare	Asthma
		Bronchospasm
		Dyspnoea
		Laryngeal oedema
		Laryngospasm
Gastrointestinal disorders	Common	Nausea
	Not known*	Vomiting*
Skin and subcutaneous tissue disorders	Very rare	Rash
		Pruritus
		Urticaria
		Quincke’s oedema

*Post-marketing experience

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.

Symptoms
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
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

Topical use. No systemic absorption of fusafungine has been shown.

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

Flavour composition 14869 (contains propylene glycol [E1520])
Ethanol, anhydrous
Saccharin
Isopropyl myristate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

15 ml type III glass bottle (plasticised with PVC) sealed with a plastic metered dose pump, containing 2.5 ml solution corresponding to approximately 50 metered doses.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Servier Laboratories (Ireland) Limited
First Floor, Block Two
West Pier Business Campus
Old Dunleary Road
Dun Laoghaire
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8 MARKETING AUTHORISATION NUMBER

PA0068/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 01 April 2007

10 DATE OF REVISION OF THE TEXT

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