Package leaflet: Information for the patient

Locabiotal® 500 micrograms per metered dose

Nasal/Oromucosal spray solution
Fusafungine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LOCABIOTAL is and what it is used for
2. What you need to know before you take LOCABIOTAL
3. How to use LOCABIOTAL
4. Possible side effects
5. How to store LOCABIOTAL
6. Contents of the pack and other information

1. What LOCABIOTAL is and what it is used for

LOCABIOTAL is a local antibiotic with anti-inflammatory properties for treatment of local infections and inflammatory conditions of the nose and throat. LOCABIOTAL is indicated in adults and adolescents (≥ 12 years old).

2. What you need to know before you use LOCABIOTAL

Do not use LOCABIOTAL:
- If you are allergic (sensitive) to the active substance fusafungine or any of the other ingredients of LOCABIOTAL (listed in section 6).
- If you have allergic tendencies or if you have asthma.
- If you have already had an attack of asthma or a feeling of breathlessness following a contraction of the airways (bronchospasm).
- The treatment is not recommended in children under 12 years.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using LOCABIOTAL.
In case of allergic reaction, stop using LOCABIOTAL and contact your doctor. LOCABIOTAL should not be readministered (see section 4 “Possible side effects”).

This medicine should be used with caution:
- If you use LOCABIOTAL for a long period of time, it may cause superinfection. If your condition does not improve in one week, treatment should be discontinued and consult your doctor.

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If you are unsure or in doubt about any of these situation, you should discuss the matter with your doctor or pharmacist before taking your medicine.

Other medicines and LOCABIOTAL
Tell your doctor or pharmacist if you are using, have recently taken or might use any other medicines.

There are no reports of reactions with other medicines.

Pregnancy and breast-feeding and fertility
It is not recommended to use LOCABIOTAL if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
LOCABIOTAL has no or negligible effect on the ability to drive or use machines.

LOCABIOTAL contains ethanol and propylene glycol
This medicine contains small amounts of ethanol (alcohol), less than 100 mg per dose and propylene glycol in the flavouring which may cause skin irritation.

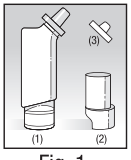
3. How to use LOCABIOTAL

Always use LOCABIOTAL exactly as your doctor or pharmacist has told you check with your doctor or pharmacist if you are not sure.

The recommended dose in general is 1 spray actuation by mouth and/or 1 spray actuation in each nostril every 4 hours. The method of use will be determined by your doctor. LOCABIOTAL should not be used for more than one week.

Method and route of administration
Oromucosal and nasal use.

Presentation: (see fig. 1)



(1) Canister with internal pump and bottle containing drug solution, with ready-to-use yellow nasal extender.

(2) Oral adapter (white).

Fig. 1.

Activation:



Before the very first use, activate the high precision pump by pressing firmly 5 times (see fig. 2).
The bottle should be held upright between the thumb and the index finger with the adapter in the upper position.

Fig. 2.

Oral use:



Fig. 3.



Fig. 4.

To administer the dose, place the oral adapter (white) in the mouth and close the lips around it; press firmly on the main adapter and hold while breathing normally (see fig. 3 and 4).

Nasal use:



Proceed in an identical manner for nasal administration after having fitted the corresponding adapter (yellow) (see fig. 5.)

Fig. 5.

The mouth and nose adapters should be disinfected every other day with cotton wool dipped in 90% alcohol.

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If you use more LOCABIOTAL than you should
In case you have taken more LOCABIOTAL or accidental use by a child, talk to a doctor or pharmacist immediately.

If you forget to use LOCABIOTAL
Use it as prescribed as soon as you remember and then go on as prescribed.
Do not take a double dose to make up for a forgotten dose.

If you stop using LOCABIOTAL
If you have any further questions on the use of this product, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:
Very common: may affect more than 1 in 10 people,
Common: may affect up to 1 in 10 people,
Uncommon: may affect up to 1 in 100 people,
Rare: may affect up to1 in 1,000 people,
Very rare: may affect up to 1 in 10,000 people.
Not known: frequency cannot be estimated from the available data

LOCABIOTAL at normal dosage may cause local stinging and occasionally irritation.

General disorders and administration site condition
Very common: sneezing, unpleasant taste in the mouth, watery eyes.
Common: nose dryness, dry throat, pricking sensation, cough, nausea.
Not known: vomiting.
These do not usually necessitate discontinuation of treatment.

Immune system disorders
Very rare: anaphylactic shock: serious allergic reaction, often life threatening allergic reaction and can be treated with adrenaline. The symptoms may include wheezing, difficulty breathing, rapid or weak pulse, low blood pressure (e.g. faintness, dizziness), and blueness of the skin.

Respiratory thoracic and mediastinal disorders
Very rare: temporary narrowing of the airways into the lungs (asthma, bronchospasms), dyspnoea (breathlessness), swelling of lips, mouth, tongue and throat (oedema), spasm of the muscles around the voice box, causing choking (laryngospasm).

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

In these cases, tell your doctor immediately.

If you experience any of these symptoms you must seek immediate medical attention and fusafungine should not be readministered.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

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5. How to store LOCABIOTAL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and container. The expiry date refers to the last day of that month.
Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What LOCABIOTAL contains

The active substance is fusafungine.
Each metered dose delivers approximately 500 micrograms of fusafungine.
The other ingredients are: saccharin, ethanol, isopropyl myristate, flavouring (contains propylene glycol [1520]).

What LOCABIOTAL looks like and contents of the pack

The solution is oily, colourless to pale yellow, clear, with a characteristic odour.
It is available as a 15 ml bottle (plasticized with PVC) sealed with a plastic metered dose pump, containing 2.5 ml solution corresponding to approximately 50 metered doses.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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