

Package leaflet: Information for the patient
LOCABIOTAL
Pressurised 125 micrograms
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. 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 further 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.

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)
- the treatment is not recommended in children under 30 months (risk of laryngospasm).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using LOCABIOTAL.

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.
- 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).

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

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 4 puffs in the mouth and 2 puffs in each nostril 4 times daily. The method of use will be determined by your doctor. LOCABIOTAL should not be used for more than one week.




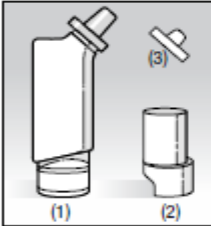
Use in children and adolescents

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

Method and route of administration

Oromucosal and nasal use

INSTRUCTIONS FOR USE



Presentation

- (1) Canister with internal pump and bottle containing drug solution.
- (2) Oral adaptor (white).
- (3) Two nasal adaptors (one yellow for adults and one transparent for children).

Activation

Before the very **first** use, the internal pump has to be activated by holding the canister upright between the thumb and index finger and pressing firmly **4 times** on the canister as shown.

Oromucosal use

Remove the yellow or transparent nasal adaptor and replace it with the white oral adaptor. The adaptor should fit tightly. Close your lips around the adaptor and press firmly **once** on the canister (as shown), holding down while breathing normally. **For adults 4 puffs are required and for children 2 to 4 puffs are required. Repeat 4 times daily for adults and children.**

Now follow the procedure for nasal use below.

Nasal use

Proceed in the same way as for oromucosal use but use the appropriate nasal adaptor (yellow for adults or transparent for children) instead of the white oral adaptor. **For adults 2 puffs in each nostril are required and for children 1 to 2 puffs in each nostril are required. Repeat 4 times daily for adults and children.**

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

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 : affects more than 1 user in 10,

Common : affects 1 to 10 users in 100,

Uncommon : affects 1 to 10 users in 1000,

Rare : affects 1 to 10 users in 10 000,

Very rare : affects less than 1 user in 10 000.

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 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. By reporting side effects you can help provide more information on the safety of this medicine.

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 50°C

The canister contains a pressurised liquid. Do not pierce the canister.

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 puff contains 125 micrograms fusafungine.

The other ingredients are saccharin, ethanol anhydrous, isopropyl myristate, flavouring, norflurane.

What LOCABIOTAL looks like and contents of the pack

The name of your medicine is Locabiotol Pressurised 125 micrograms.

One canister contains 10 ml of solution of fusafungine, designed to give approximately 400 puffs.

Each pack contains one canister and three adaptors, one for oral use, two for nasal use (one for adults, one for children).

Marketing Authorisation Holder and Manufacturers:

Marketing Authorisation Holder
Servier Laboratories (Ireland) Ltd,
First Floor, Block Two,
West Pier Business Campus,
Old Dunleary Rd.,
Dun Laoghaire,
County Dublin
Ireland

Manufacturers:

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905 route de Saran,
45520 Gidy, France
or
EGIS Lacta Gyógyszergyár,
9900 Körmend,

Mátyás Király út 65,
Hungary

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