

Flusterix[®]

Fucidic Acid
cream 2%



PATIENT INFORMATION LEAFLET

1. DETERMINATION OF THE MEDICINAL PRODUCT

1.1 Name: Flusterix[®]

1.2 Composition:

Active ingredient: Fusidic Acid.

Excipients: Butylated hydroxyanisole, Cetyl alcohol, Glycerol, Potassium sorbate, Paraffin liquid, Polysorbate 60, White soft paraffin, Purified water.

1.3 Pharmaceutical form: Cream

1.4 Content: 1gr Flusterix cream contains 20 mg Fusidic acid.

1.5 Description-Package: Each box contains an aluminum tube containing 15g of cream with a polyethylene screw safety cap and a leaflet

1.6 Pharmacotherapeutic group: Antibiotics for topical use (ATC D06AX01).

1.7 Marketing Authorization Holder - Manufacturer: IASIS PHARMA HELLAS S.A

137, Filis Ave. 134 51 Athens, Greece. Tel: +30210 2311031

2. WHAT YOU NEED TO KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

2.1 General information

Flusterix is an antibiotic with a strong antimicrobial action against a number of Gram-positive microorganisms. Staphylococci, including strains resistant to penicillin, are particularly sensitive to Flusterix.

Topical application of Flusterix is therapeutically effective due to its strong antimicrobial action against microorganisms responsible for skin infections, as well as due to its unique ability to penetrate into intact skin.

2.2 Indications

Treatment of staphylococcal skin infections and skin abscesses..

2.3 Contraindications

It is contraindicated in case of allergy to fusidic acid and its salts or in case of infection by resistant organisms, such as *Pseudomonas aeruginosa*

2.4 Special warnings and precautions for use

2.4.1 General: When used for a prolonged period of time, resistant microbe strains may develop. Caution is required so as to avoid contact with eyes.

2.4.2 Elderly: Same as for the adults

2.4.3-4 Pregnancy and lactation: Safety during pregnancy and lactation has not been established. Consult your doctor before using it.

2.4.5 Children: Consult your doctor.

2.4.6 Effects on ability to drive and use machines: Not reported.

2.4.7 Special warnings regarding excipients: No special warnings about the product's excipients have been reported.

2.5 Interaction with other medicines or substances:

Not reported.

2.6 Posology

Flusterix cream is applied topically on the infected area 2-3 times per day for a maximum period of seven (7) days.

It can be used with or without dressing. When used with dressing, less frequent application is recommended.

2.7 Overdose - Treatment

Due to its topical application, overdose cannot occur.

In case of accidental swallow contact your doctor.

2.8 Undesirable effects

Rare topical reactions that manifest themselves through skin rash and irritation in the application area.

2.9 What the patients needs to know if they miss a dose

If you must take the medicine continuously and you miss a dose, you should take it as soon as possible.

If, however, it is almost time for your next dose, do not take the missed dose, just continue the treatment.

2.10 Product expiry date

It is indicated both on the outer and inner packaging.

If the expiry date has passed, do not use the medicine.

2.11 Special precautions for storage

Flusterix cream must be stored at temperature not exceeding 25°C in a dry place.

2.12 Package leaflet last revision date: 6/2007

3. INFORMATION ON THE RATIONAL USE OF DRUGS

- This medicine was prescribed by your doctor only for a specific medical problem. You must not pass it to other people or use it for any other condition without previously consulting your doctor.
- If during treatment there is a problem with the medicine, inform your doctor or pharmacist.
- If you have any questions about the information on your medicine or you need more information about your medical problem, do not hesitate to ask your doctor or pharmacist.
- The prescribed medicine should be taken in accordance with the instructions given to you, so as to be effective and safe.
 - For your safety and health, it is essential to carefully read all information regarding the medicine prescribed to you.
 - Do not keep medicines in bathroom cabinets, because heat and humidity may alter the medicine and render it harmful to your health.
 - Do not keep medicines no longer needed or expired.
 - For additional safety, keep all your medicines out of reach of children.

4. MODE OF ADMINISTRATION

Flusterix cream is a prescription medicine.