

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucidin® H 20 mg/10 mg/g cream fusidic acid/hydrocortisone acetate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1. What Fucidin® H is and what it is used for
2. Before you use Fucidin® H
3. How to use Fucidin® H
4. Possible side effects
5. How to store Fucidin® H
6. Further information

1. WHAT FUCICDIN® H IS AND WHAT IT IS USED FOR

Fucidin® H combines the antibacterial action of fusidic acid with the anti-inflammatory effect of hydrocortisone acetate.

Fucidin® H cream is indicated for the treatment of dermatitis, including atopic dermatitis and contact dermatitis, where an infection with bacteria sensitive to fusidic acid is suspected or confirmed.

2. BEFORE YOU USE FUCICDIN® H

Do not use Fucidin® H

Hypersensitivity to fusidic acid/sodium fusidate, hydrocortisone acetate or to any of the excipients listed in section.

Due to the content of corticosteroid, Fucidin® H is contraindicated in the following conditions:

Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment.

Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy.

Perioral dermatitis and rosacea.

Take special care with Fucidin® H

Long-term continuous topical therapy should be avoided, particularly in infants and children, since subadrenal suppression may occur.

Due to the content of corticosteroid, Fucidin® H should be used with care near the eyes. Avoid getting Fucidin® H into the eyes.

Fucidin® H cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate. These excipients may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Effects on ability to drive and use machines

Fucidin® H cream has no or negligible influence on the ability to drive and use machines.

3. HOW TO USE FUCIDIN® H

Always use Fucidin® H cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Fucidin® H cream is applied 2-3 times for up to weeks.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fucidin® H cream can cause side effects, although not everybody gets them.

The most frequently reported undesirable effects on Fucidin® H cream are various application site reactions, such as pruritus, burning and irritation.

Uncommon adverse reactions are: dermatitis contact, eczema (condition aggravated), rash, hypersensitivity.

As with all other corticosteroids atrophy, dermatitis (incl. dermatitis contact, dermatitis acneiform and perioral dermatitis), skin striae, telangiectasia, rosacea, redness (erythema), depigmentation, hypertrichosis, hyperhidrosis (excessive sweating in different body parts), although rare, may occur.

Reversible subadrenal suppression may occur following systemic absorption of topical corticosteroids, particularly during prolonged therapy.

Raised intra-ocular pressure and glaucoma may also occur after topical use of corticosteroids near the eyes, particularly with prolonged use and in patients predisposed to developing glaucoma.

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.

5. HOW TO STORE FUCIDIN® H

Keep out of the reach and sight of children

Do not store above 30° C

Period of use after first opening: 3 months

Do not use after the expiry date indicated on the package.

Medicines should not be disposed of 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. FURTHER INFORMATION

What Fucidin® H cream contains

The active substances are:

Fusidic acid and hydrocortisone acetate

One gram of cream contains 20 mg fusidic acid and 10 mg hydrocortisone acetate

The other ingredients are:

Butylhydroxyanisole, cetyl alcohol, glycerol (85 per cent), liquid paraffin, polysorbate 60, potassium sorbate, white soft paraffin, hydrochloric acid, all-rac-tocopherol, purified water.

What Fucidin® H cream looks like and the contents of the pack

15 g tubes

Marketing Authorization Holder

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

Manufacturer:

LEO Laboratories Ltd. (Leo Pharma)
285 Cashel Road
Dublin 12
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