PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucicort 20 mg/1 mg/g cream
fusidic acid/betamethasone

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 FUCICORT IS AND WHAT IT IS USED FOR

Fucicort combines the antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone.

Fucicort cream is indicated for treatment of inflammatory dermatoses, such as atopic eczema and contact dermatitis where bacterial infection is present or likely to occur such one.

2. BEFORE YOU USE FUCICORT

Do not use Fucicort

Hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or to any of the excipients.

Due to the content of corticosteroid, Fucicort is contraindicated in the following conditions:

Systemic fungal infections

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 Fucicort

Long-term continuous topical therapy should be avoided, particularly in infants and children. The subadrenal inhibition can occur even without using an occlusive dressing. Fucicort cream

must be used with caution in the treatment of large areas of the body, face and cutaneous folds.

Due to the content of corticosteroid, Fucicort should be used with care near the eyes. Avoid getting Fucicort into the eyes. In case of sudden discontinuation of treatment after long-term use, a rebound effect may be observed in the form of redness and burning sensation of the skin.

Due to the content of betamethasone valerate, prolonged topical use of Fucicort may cause skin atrophy.

Fucicort cream contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

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
Fucicort has no or negligible influence on the ability to drive and use machines.

3. HOW TO USE FUCICORT

Fucicort should be applied to the affected area twice daily.

For cutaneous use.

If you have used more Fucicort than you should
If the dose is exceeded, or the period of usage is extended beyond the medical recommendation, there is risk:

- that the skin at the application site becomes thinner and small veins could be seen, particularly if the cream is used in the skin folds or if the treated area is covered by plaster/bandage;
- that too much corticosteroid is absorbed into the blood and systemic effects may occur; in this case the face may become puffy.

Infants and children are more exposed to these risks and especially if the treated area is covered by clothing or dressings.

4. POSSIBLE SIDE EFFECTS

Though most people find this cream causes no problems, like with any other similar treatments, some patients might get adverse reactions.

Uncommon adverse reactions are: burning sensation of the skin, pruritus, eczema (condition aggravated), dermatitis contact, dry skin, hypersensitivity, application site pain, application site irritation.

Rare adverse reactions are: urticaria, reddeness (erythema), rash, application site swelling, application site vesicles

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

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

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:

Bulgarian drug agency
8 Damyan Gruev Str.
1303 Sofia
Tel.: + 359 2 890 34 17

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

5. HOW TO STORE FUCICORT

Keep out of the reach and sight of children
Do not store above 30^{o} C
Period of use after first opening: 3 months
Do not use after the expiry date indicated on the package.

6. FURTHER INFORMATION

What Fucicort contains
The active substances are:
Fusidic acid and betamethasone
One gram of cream contains 20 mg fusidic acid (as hemihydrate) and betamethasone (as betamethasone valerate).

The other ingredients are:
Macrogol cetostearyl ether
Cetostearyl alcohol
Chlorocresol
Sodium dihydrogen phosphate dihydrate
Liquid paraffin
White soft paraffin
Sodium hydroxide
All-rac-tocopherol
Purified water

What Fucicort looks like and the contents of the pack
15 g tubes and 20 g tubes

Marketing Authorization Holder

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

Manufacturers:

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

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Detailed information on this medicine is available on the web site of Bulgarian drug agency.