

FUCIDIN HYDROCORTISONE 20 MG/G + 10 MG/G, cream

Fusidic acid and hydrocortisone

Read the entire package leaflet carefully before you start using this medicine.

- Keep this package leaflet. You may want to read it again later.
- If you have further questions, please contact your doctor or pharmacist.
- This medicine has been prescribed for you personally. 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 listed significantly affect you or if you notice side effects not listed in this leaflet, please inform your doctor or pharmacist.

This package leaflet includes:

1. What is Fucidin Hydrocortisone 20 mg/g + 10 mg/g, cream and what is it used for?
2. What should you consider before using Fucidin Hydrocortisone 20 mg/g + 10 mg/g, cream?
3. How to use Fucidin Hydrocortisone 20 mg/g + 10 mg/g, cream?
4. What side effects are possible?
5. How to store Fucidin Hydrocortisone 20 mg/g + 10 mg/g, cream?
6. Further information

1. WHAT IS FUCIDIN HYDROCORTISONE 20 MG/G + 10 MG/G, CREAM AND WHAT IS IT USED FOR?

Cream with an antibiotic (fusidic acid) and an anti-inflammatory substance derived from cortisone (hydrocortisone acetate).

Fucidin Hydrocortisone is recommended for eczema and skin inflammation associated with a bacterial infection.

2. WHAT SHOULD YOU CONSIDER BEFORE USING FUCIDIN HYDROCORTISONE 20 MG/G + 10 MG/G, CREAM

Fucidin Hydrocortisone must not be used:

- If you are allergic to fusidic acid, hydrocortisone, or any of the other ingredients of Fucidin Hydrocortisone.
- If you have a skin condition caused by viruses (such as cold sores, chickenpox, shingles), fungal infections, skin tuberculosis, or syphilis.
- In case of skin inflammation around the mouth.
- In case of skin tissue atrophy.
- In case of normal or reddish acne.
- On skin wounds or ulcers

Special caution is required when using Fucidin Hydrocortisone:

- If you apply the cream around the eyes. Fucidin Hydrocortisone must not be applied on the eyelids or around the eyes.
- If you use the cream for a long time. Long-term use of corticosteroid derivatives must be avoided in children.

- Follow the doctor's instructions. The duration of treatment must be limited to the period necessary for healing the injury, also to prevent resistance.
- If irritation occurs, the treatment must be discontinued.
- When corticosteroids are applied to large skin areas, under occlusive dressings, on mucous membranes, or in skin folds, systemic side effects may occur. Fucidin Hydrocortisone must not be applied on mucous membranes and open wounds.
- Corticosteroid derivatives delay scar formation.
- If you have fragile superficial blood vessels or itching at the anus or genitals.
- In these cases, Fucidin Hydrocortisone should be avoided.
- The application should be limited to 2 weeks.

Systemic therapy is necessary if the bacterial infection persists.

Consult your doctor if any of the above warnings apply to you or have applied in the past.

When using Fucidin Hydrocortisone with other medications

Please inform your doctor or pharmacist if you are using or have recently used other medications, even if they are non-prescription medications.

When using Fucidin Hydrocortisone together with food and drinks

Not applicable.

Pregnancy

There are no clinical data available on the use of fusidic acid during pregnancy. Animal studies do not indicate direct or indirect harmful effects on pregnancy, embryonic/fetal development, birth, or postnatal development (1,2,3). The absorption of hydrocortisone acetate after local administration is limited, and the data on use during pregnancy do not indicate adverse effects on the fetus/newborn (4,5,6). Caution is advised when prescribing to pregnant women.

Lactation

No effects on the infant are expected, as the systemic exposure of the nursing woman to fusidic acid and hydrocortisone acetate after local application (7, 8) is negligible. Fucidin Hydrocortisone can be used during lactation. When applied to the nipple, all cream residues must be removed from the nipple before breastfeeding.

Consult your doctor or pharmacist for advice before taking any medication.

Ability to drive and use machines

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

Important information about some of the other ingredients of Fucidin Hydrocortisone Fucidin Hydrocortisone cream contains butylhydroxyanisole and cetyl alcohol, which may cause local skin reactions (e.g., contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes.

3. HOW TO USE FUCIDIN HYDROCORTISONE 20 MG/G + 10 MG/G, CREAM?

Always use Fucidin Hydrocortisone exactly as your doctor has instructed. Please consult your doctor or pharmacist if you are not entirely sure.

Apply three times daily to the previously cleaned affected skin. Do not damage the skin by excessive rubbing when applying the cream.

If you have used more Fucidin Hydrocortisone than you should:

If you have used too much Fucidin Hydrocortisone, you should contact your doctor, pharmacist, or poison control center (070/245 245) immediately.

To date, no cases of overdose have been described. With multiple or excessive applications, general side effects may occur.

If you forget to use Fucidin Hydrocortisone:

Apply the usual amount of Fucidin Hydrocortisone cream at the next opportunity. You do not need to apply a double amount of cream.

If you stop using Fucidin Hydrocortisone:

After the end of treatment, it is possible that the skin condition may recur.

If you have further questions on the use of the medicine, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE

Like all medicines, FUCIDIN HYDROCORTISONE can have side effects, but not everyone will experience them.

- The most common side effect is irritation at the application site.
- Itching
- Skin irritation
- Temporary burning or stinging sensation of the skin
- Rash
- Worsening of eczema
- Allergic reactions are extremely rare.
- The following side effects of topically applied corticosteroids, especially under occlusive dressings, have been reported:
 - Burning sensation, itching, irritation, dryness, inflammation of hair follicles (folliculitis), excessive hair growth (hypertrichosis), acne-like rash, skin discoloration, rash around the mouth, contact dermatitis, skin softening, additional infection, thinning of the skin, stretch marks, small blisters.

As with all antibiotics, there is a risk of secondary infection by resistant germs.

If you notice a side effect not listed in this leaflet or consider it serious, you should inform your doctor or pharmacist.

5. HOW TO STORE FUCIDIN HYDROCORTISONE 20 MG/G + 10 MG/G, CREAM?

Keep medicines out of the reach of children.

Do not store above 25°C

Do not use the medicine after the expiry date stated on the packaging after the initials EX. (month/year). The abbreviation EX. means that the medicine expires on the last day of the month indicated after the abbreviation. This date must not be exceeded.

The medicine must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicine if you no longer need it. This measure helps protect the environment.

6. ADDITIONAL INFORMATION

What Fucidin Hydrocortisone contains

The active substances are fusidic acid (anhydrous) 20 mg/g + hydrocortisone acetate 10 mg/g

Other ingredients (excipients) are butylhydroxyanisole – cetanol – glycerol 85% - liquid paraffin – potassium sorbate – polysorbate 60 – white petrolatum – all-rac- α -tocopherol - purified Water

What Fucidin Hydrocortisone looks like and contents of the pack Cream, available in tubes of 15 g and 30 g.

Pharmaceutical entrepreneur and manufacturer

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Prescription only.

This package leaflet was last approved on 28 April 2011

Detailed information about this medicine is available on the website www.faggafmpsbe

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