

The PL includes alternative texts for different legal status in different countries as follows:

- [Boxed texts] are only applicable for OTC versions.
- [Grey-shaded texts in brackets] are only applicable for prescription versions.

Package leaflet: Information for the user

Hydrokortison Evolan 10 mg/g cream

Hydrocortisone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

[Read all of this leaflet carefully before you start using this medicine because it contains important information for you.]

- 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 only. 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. This includes any possible side effects not listed in this leaflet. See section 4.]

What is in this leaflet

1. What Hydrokortison Evolan is and what it is used for
2. What you need to know before you use Hydrokortison Evolan
3. How to use Hydrokortison Evolan
4. Possible side effects
5. How to store Hydrokortison Evolan
6. Contents of the pack and other information

1. What Hydrokortison Evolan is and what it is used for

Hydrokortison Evolan cream is a mild acting hydrocortisone cream with anti-inflammatory and antipruritic effect.

Hydrokortison Evolan is used to treat mild eczema caused by such as soap, detergents, cosmetics, insect's bites and sunburn.

[Hydrokortison Evolan can, after prescription from a doctor, also be used to treatment of itching in the rectum.]

2. What you need to know before you use Hydrokortison Evolan

Do not use Hydrokortison Evolan

- If you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Do not use Hydrokortison Evolan on wounds or in the area around the eyes.
- Perioral dermatitis, rosacea and acne should not be treated with corticosteroids. If you have a skin infection, do not use Hydrokortison Evolan unless the infection is treated at the same time. Consult your doctor in those cases.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children

Children below the age of two years shall only be treated after recommendation by a doctor.

Other medicines and Hydrokortison Evolan

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Hydrokortison Evolan can be used during pregnancy and breast-feeding. However, prolonged use and large amount of cream should be avoided.

Driving and using machines

Hydrokortison Evolan has no influence on the ability to drive and use machines.

Hydrokortison Evolan contains cetostearyl alcohol and parahydroxybenzoic esters

- the cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)
- the cream contains methyl parahydroxybenzoate, ethyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed)

3. How to use Hydrokortison Evolan

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor if you are not sure.

[Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.]

Apply a thin layer morning and evening or use as recommended by your doctor.

After 3-4 days, the number of applications with Hydrokortison Evolan can normally be reduced and the treatment can be altered with a moisturising cream.
If the symptoms not have improved after 1 week, contact your doctor for advice.

If you use more Hydrokortison Evolan than you should

Contact your doctor, hospital or poison information centre if you have used too much medicine or if a child by accident has taken the medicine. Overdose is not expected since the cream only shall be used on the skin.

If you forget to use Hydrokortison Evolan

Apply a thin layer next morning or evening.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon (occurs for more than 1 of 100 but more less than 1 of 1000 user):

- Skin irritation, contact allergy in form of increased itching, redness and irritation.
- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrokortison Evolan

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 tube.
The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to do with medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydrokortison Evolan contains

- The active substance is hydrocortisone 10 mg/g.
- The other ingredients are cetostearyl alcohol, macrogol cetostearyl ether, light liquid paraffin, white soft paraffin, citric acid (E330), sodium citrate (E331), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), water.

What Hydrokortison Evolan looks like and contents of the pack

Appearance: White to yellow-white cream

Package sizes: Tubes with 20 g, 50 g and 100 g.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

This leaflet was last revised in

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Detailed information on this medicine is available on the website of {name of MS Agency (link)}