

PACKAGE LEAFLET: INFORMATION FOR THE USER

HYDROCYCLIN

1% + 3% ointment

HYDROCORTISONE, OXYTETRACYCLINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What HYDROCYCLIN is and what it is used for
2. Before you take HYDROCYCLIN
3. How to use HYDROCYCLIN
4. Possible side effects
5. How to store HYDROCYCLIN
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1. WHAT HYDROCYCLIN IS AND WHAT IT IS USED FOR

HYDROCYCLIN ointment contains two active substances: hydrocortisone and oxytetracycline.

Hydrocortisone is a corticosteroid that is used for reducing signs of inflammation of the skin caused due to allergy, infection or injury.

Oxytetracycline belongs to the group of medicines called tetracycline antibiotics. It is used to treat infections caused by bacteria and other microorganisms.

HYDROCYCLIN ointment is used to treat:

- inflammatory skin changes (exudative and secondarily infected eczema, including atopic eczema);
- primary contact dermatitis (an allergic skin lesions eg. After contact with certain cosmetic products, plants or medicines);
- allergic and seborrheic dermatitis;
- secondarily infected lesions on the skin after insect bites.

Not recommended for use in children, and in adults, the ointment is carefully applied after cleaning of the diseased skin area two to four times per day in a thin layer. The treatment should not last longer than seven

days without clinically apparent improvement, because prolonged use of corticosteroids may mask the symptoms of the infection.

HYDROCYCLIN ointment is only applied to the skin.

2. BEFORE YOU TAKE HYDROCYCLIN

Do not take HYDROCYCLIN

- If you have ever had an allergic reaction to any of the components of this medicine. It could manifest itself in the form of itching, redness of the skin or difficulty breathing.
- If you have a skin infection that is manifested in the form of blisters or yellow scabs (primary bacterial infection), for example. impetigo, ulcers (furunculosis).
- If you are pregnant, planning to become pregnant or if you are breast-feeding.
- If the patient is an infant or child is in the stage of eruption of permanent teeth.

If any of the above applies to you, consult your doctor.

Take special care with HYDROCYCLIN

If you intend to apply this medicine to large areas of the skin or under occlusion, consult your doctor or pharmacist before using this medicine.

Taking other medicines

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

The medicine HYDROCYCLIN should not have effects on any other medicines you are taking. If you have any doubts regarding the concomitant use of other medicines, consult your doctor or pharmacist.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Do not use this medicine if you are pregnant, if you are trying to become pregnant or if you are breast-feeding.

The application of this medicine is contraindicated during pregnancy and lactation. Consult with your doctor.

Other warnings

The medicine HYDROCYCLIN contains lanolin in its composition, which may cause local skin reactions (eg, contact dermatitis).

3. HOW TO USE HYDROCYCLIN

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

Adults and the elderly

Carefully clean the affected area of the skin, and then apply a thin layer of ointment, 2 to 4 times a day. Ointment can be applied with sterile gauze in the presence of infection.

Do not interrupt with application of HYDROCYCLIN ointments as soon as you notice the first signs of improvement on the treated skin.

If after 7 days of starting treatment there is no improvement, consult your doctor.

This medicine is intended for external use. Do not use it to treat eye infections.

Children

Application of HYDROCYCLIN ointment is not recommended.

If you use more HYDROCYCLIN than you should

Immediately contact your doctor if you swallow this medicine.

It is not expected that a larger quantity of medicine HYDROCYCLIN ointment may cause life-threatening symptoms.

If you forget to take HYDROCYCLIN

If you forgot to apply HYDROCYCLIN ointment do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

If you notice any of the following symptoms, immediately contact your doctor or pharmacist:

- wheezing, shortness of breath or chest tightness;
- swelling of the eyelids, face or lips;
- bumps on the skin or spot redness accompanied by itching.

The following undesirable effects may occur at the administration site:

- burning sensation;
- itching;
- irritation;
- dryness;
- skin rash or allergic reaction;
- acne;
- thinning or softening of the skin;
- spread or worsening of the infection;
- inflammation of the hair follicles (folliculitis);
- increased hair growth (hypertrichosis);
- changes in the skin color (hypopigmentation);
- rash caused by heat;
- stretch marks (red lines on the skin).

Reporting of suspected 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.

5. HOW TO STORE HYDROCYCLIN

Keep out of the reach and sight of children.

Throw the opened tube 30 days after opening to prevent infection. Write down the date when you opened the tube.

Store below 25 °C.

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.

The shelf life of medicine is 3 years from the date of manufacture indicated on the packaging of the medicine.

6. FURTHER INFORMATION

What HYDROCYCLIN contains

Active ingredients:

1 g of ointment contains 10 mg of hydrocortisone, and 30 mg of oxytetracycline hydrochloride.

Other ingredients:

paraffin, solid; paraffin, liquid light; lanolin and paraffin, white soft.

What HYDROCYCLIN looks like and contents of the pack

Appearance:

Homogeneous yellow ointment.

Tube 5 g:

The inner packaging of the medicine is an aluminum tube with open throat with a stylus and a plastic cap containing 5 g of ointment.

Tube 20 g:

The inner packaging of the medicine is an aluminum tube with closed throat with a plastic cap with pin and rubber ring containing 20 g of ointment.

The outer packaging of the medicine is a folding cardboard box containing the tube of 5 g or 20 g of ointment and patient information leaflet.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Galenika ad, Batajnički drum bb, Belgrade, Serbia