PACKAGE LEAFLET: Information for the user

HYDROCUTAN

Ointment – 1%

(Hydrocortisone)

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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT HYDROCUTAN IS AND WHAT IT IS USED FOR?

Hydrocutan 1% ointment contains the active substance hydrocortisone which is a glucocorticoid. It is used for the treatment of inflammatory skin diseases in which weak, topical glucocorticoids are indicated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HYDROCUTAN?

Hydrocutan should not be used in:

hypersensitivity to any of its ingredients, herpes simplex infections, varicella, vaccination reactions, specific skin processes (e.g., syphilis, tuberculosis), fungal infections, bacterial skin

processes, rosacea and perioral dermatitis.
Hydrocutan should not be used at or in the eye, in mucous membranes, as well as in diseases associated with an impairment of the hypothalamic-pituitary regulation (e.g. Cushing's syndrome).

Take special care while using Hydrocutan:
Please talk to your doctor or pharmacist before using Hydrocutan.
Hydrocutan should be used on the face only with particular caution.
In case of treatment in the genital or anal area, the excipients white soft paraffin and light liquid paraffin can lead to a reduction in the tensile strength and thus compromise the safety of condoms when using condoms made of latex at the same time.
If you experience blurred vision or other visual disturbances, contact your doctor.

While using Hydrocutan ointment 1 % with other drugs:
Please tell your doctor or pharmacist if you are taking / using other medicines, have recently taken / used other medicines or plan to take / use them, including medicines obtained without a prescription.
When used properly, no systemic absorption of steroid is expected. If systemic absorption occurs, the following interactions are to be expected:

- cardiac glycosides: glycosides effect is enhanced by potassium deficiency
- saluretics: additional potassium excretion
- antidiabetics: blood glucose decrease reduced
- coumarin derivatives: anticoagulant effect attenuated
- rifampicin, phenytoin, barbiturates: corticoid effect attenuated
- nonsteroidal anti-inflammatory / anti-rheumatic drugs: increased risk of gastrointestinal bleeding.

Pregnancy and breastfeeding

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

Pregnancy

There are no adequate data for the use of hyrocortisone 1% ointment in pregnant women. In animal studies, glucocorticoids have shown harmful effects for the offspring. In human fetuses also is discussed an increased risk for oral clefts in the systemic use of glucocorticoids during the first trimester. Studies in animals have also shown that administration of glucocorticoids in therapeutic doses during pregnancy delays offspring growth and also may cause cardiovascular disease and / or metabolic diseases in adulthood and a permanent change in the behavior.
If you are pregnant, you may use Hydrocutan only if your doctor considers it necessary. Please contact your doctor immediately.

Breastfeeding

The active ingredient of this ointment passes into breast milk. When higher doses are used or it is used for long-term, breastfeeding should be discontinued.
During breastfeeding avoid babies contact with the affected skin area. Breastfeeding mothers should not apply hydrocortisone to the breast area.

Driving and using machines

It is not necessary to take special precautions.

Important information about some of the ingredients of Hydrocutan:

Stearyl alcohol may cause local skin irritation (e.g. contact dermatitis).

3. HOW TO USE HYDROCUTAN?

Always use Hydrocutan 1% ointment exactly as your doctor has told you. Please check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, the usual dose is:

At the beginning of therapy, the ointment is applied thinly 2 - 3 times daily to the affected skin and massaged into it. The skin should be neither damaged by too vigorous rubbing or excessive high pressure. Prior to application, the skin should be thoroughly cleaned to prevent infection. After improvement, the number of applications is reduced. It is then sufficient a daily use in 2 - 3-day intervals.

Method of administration

For use on the skin.

Duration of use:

The doctor will decide on the duration of treatment. It will depend on the type, gravity and the progress of the disease.

If you feel that the effects of Hydrocutan are too strong or too weak, please talk to your doctor or pharmacist.

If you use more Hydrocutan than you should:

Reduce the dose or, if possible, discontinue the drug after high-dose and long-term (longer than four weeks) use.

With long-term (longer than four weeks), large-area (more than 1/10 of the body surface) use, especially under occlusive dressings or on severely damaged skin, the active substance can be absorbed into the body and thus cause side effects such as inhibition of the adrenal gland or Cushing syndrome (trunk obesity, full moon face). In this case, see your doctor.

If you forget to use Hydrocutan:

Continue treatment as prescribed.

If you stop using Hydrocutan:

The disease may worsen.

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

4. POSSIBLE SIDE EFFECTS

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

Possible side effects

On extended use, skin atrophy, telangiectasia, striae, acne, perioral dermatitis and secondary infections may occur.

During long-term use in high doses or over large areas, possible systemic effects may be observed.

If it is used under occlusive dressing, the following may occur: miliaria, hypopigmentation, maceration of the skin, folliculitis, skin dryness, burning, itching, skin irritation, favouring of secondary infections. The wound healing is delayed.

Especially in children and infants appropriate precautions should be taken.

Uncommon (1 to 10 users in 1,000): allergic skin reactions.

Not known (frequency cannot be determined from the available data): blurred vision.

General side effects as a result of the absorption of the active ingredient in the body, such as a reduction in the adrenal function, symptoms of Cushing's syndrome and an increase in intraocular pressure, are also conceivable.

With long-term, high-dose use of hydrocortisone on the skin, especially under occlusive dressing (e.g. in the diaper area), so much active substance can be absorbed into the body that the body's own ACTH release is inhibited; this can lead to a drop in the level of cortisol in the blood. The possibility of general side effects must be considered especially in children.

If side effects occur, stop the treatment and appropriate precautions should be taken.

If any of the mentioned side effects disturbs you, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE HYDROCUTAN?

Keep out of the reach and sight of children.

Store below 25°C!

Do not use the drug after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Hydrocutan 1% ointment contains:

The active substance is hydrocortisone.

1 g ointment contains 10 mg hydrocortisone.

The excipients are: white soft paraffin, light liquid paraffin, stearyl alcohol, sorbitane sesquioleate, polysorbate, disodium EDTA, purified water.

Contents of the pack:

Carton box with 1 tube of 30 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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