

PACKAGE LEAFLET: INFORMATION FOR THE USER

Hydrocortisyl[®] Skin Ointment 1%

Hydrocortisone

Is this leaflet hard to see or read?

Phone 01 403 5600 for Help.

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. 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 of the side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

In this leaflet:

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

1. What Hydrocortisyl Skin Ointment is and what it is used for

The name of your medicine is Hydrocortisyl Skin Ointment 1%. Hydrocortisyl Skin Ointment contains the active ingredient Hydrocortisone 1% w/w.

- Hydrocortisone belongs to a group of medicines called corticosteroids. It works by lowering the production of substances that cause inflammation. This helps lower swelling and itching.

Hydrocortisyl Skin Ointment can be applied to the skin to treat a variety of skin conditions sensitive to corticosteroid treatment such as itching, eczema, dermatitis (inflamed skin), including the skin of the outer ear (otitis externa) and of your scalp, and rashes due to allergic reactions.

2. Before you use Hydrocortisyl Skin Ointment

Do not use this medicine and tell your doctor if:

- You are allergic (hypersensitive) to hydrocortisone or any of the other ingredients of Hydrocortisyl Skin Ointment (listed in Section 6 below). Signs of an allergic

- reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have any kind of infection this includes infections caused by viruses, bacteria or fungus or if you are being treated for tuberculosis.
 - You have perioral dermatitis, acne, acne rosacea or psoriasis. Use of this product if you have psoriasis may cause your psoriasis to get worse or it could make your psoriasis return once you stop using the ointment.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor before using Hydrocortisyl Skin Ointment.

Children

Do not use in children under 12 years of age without medical supervision. If advised to use this product it must be applied sparingly over a small area once or twice a day for no longer than 7 days.

Care must be taken with children under 3 years of age using this medicine for a long time (longer than 3 weeks), as there is a risk of 'adrenal suppression' and stunted growth. Please see Section 4. 'Possible side effects' for further information.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Hydrocortisyl Skin Ointment can affect the way some other medicines work. Also some medicines can affect the way Hydrocortisyl Skin Ointment works.

Pregnancy and breast-feeding

This product should not be used in pregnancy or during breast-feeding unless considered essential by your doctor.

Talk to your doctor before using this medicine if

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Important information about some of the ingredients of Hydrocortisyl Skin Ointment

This medicine contains wool fat (lanolin) which may cause local skin reactions such as contact dermatitis. Contact dermatitis causes redness, itching or irritation of the skin.

3. How to use Hydrocortisyl Skin Ointment

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Using this medicine

- Do not use for longer than 7 days
- Apply sparingly to the affected area of the skin one to four times a day. When skin condition improves, frequency of application can be gradually reduced.
- Do not cover the area with a plaster or any dressings (including nappies).
- Do not use on the eyes or face, anogenital region or on broken or infected skin e.g. cold sores, acne or athletes foot.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

Use in Children and Adolescents

Do not use in children under 12 years of age without medical supervision. If advised to use this product it must be applied sparingly over a small area once or twice a day for no longer than 7 days.

Care must be taken with children under 3 years of age using this medicine for a long time (longer than 3 weeks), as there is a risk of 'adrenal suppression' and stunted growth. Please see Section 4. 'Possible side effects' for further information.

How to apply this medicine

If your doctor has asked you to apply some ointment to the affected area, follow the instructions below on how to apply this medicine:

- Wash your hands
- Squeeze a small amount of the ointment onto your fingertip
- Gently rub a small layer of ointment over the inflamed, itchy area
- Wash your hands

If you use more Hydrocortisyl Skin Ointment than you should

Let your doctor know if you have used this ointment for more than 7 days by mistake.

If you forget to use Hydrocortisyl Skin Ointment

If you forget to use your ointment, use it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, Hydrocortisyl Skin Ointment can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if the following side effect gets serious or lasts longer than a few days, or you notice any side effects not listed in this leaflet:

- Striae (narrow bands which appear on the skin) can sometimes occur especially in the skin folds
- Allergic (hypersensitive) reaction to hydrocortisone. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Local thinning of the skin and more visible blood vessels and veins, particularly on the face.

If you use this ointment for a long time, or under dressings or nappies, it is possible that you could get something called ‘adrenal suppression’. Signs include lack of appetite, pain in the stomach, weight loss, feeling sick or being sick, lack of concentration, a feeling of hunger, nervousness and fits.

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 to the Irish Medicines Board. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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

5. How to store Hydrocortisyl Skin Ointment

Keep this medicine in a safe place out of the reach and sight of children.

Do not use Hydrocortisyl Skin Ointment after the expiry date which is stated on the label, carton or tube after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the medicine in the pack in which it was given to you.
Discard 4 weeks after first opening.

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.

6. Contents of the pack and other information

What Hydrocortisyl Skin Ointment contains

- The active substance is hydrocortisone. Each gram of this medicine contains 0.01g hydrocortisone.
- The other ingredients are wool fat, liquid paraffin and white soft paraffin.

What Hydrocortisyl Skin Ointment looks like and contents of the pack

Hydrocortisyl Skin Ointment is a smooth, yellowish-white ointment. It is available in a 15 gram aluminium tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Dublin 24
Tel: 01 403 5600
Fax: 01 403 5687
email: iemedinfo@sanofi.com

Manufacturer

Sanofi Winthrop Industrie
196 rue du Maréchal Juin
45200 Amilly
France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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