
SCHEDULING STATUS: [S4] Patient Information Leaflet

HYDROCORTISONE CREAM GLENMARK (Cream)

Hydrocortisone valerate

Read all of this leaflet carefully before you use HYDROCORTISONE CREAM GLENMARK

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **HYDROCORTISONE CREAM GLENMARK** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What HYDROCORTISONE CREAM GLENMARK is and what it is used for

HYDROCORTISONE CREAM GLENMARK contains a medicine called hydrocortisone valerate. It belongs to a group of medicines called corticosteroids. **HYDROCORTISONE CREAM GLENMARK** is indicated for the relief of the non-infected inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in adult patients.

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2. What you need to know before you use HYDROCORTISONE CREAM GLENMARK

Do not use HYDROCORTISONE CREAM GLENMARK:

- If you are hypersensitive (allergic) or have had a previous allergic reaction to hydrocortisone valerate or to any of the other ingredients of **HYDROCORTISONE CREAM GLENMARK** (see *section 6*)
- If you are pregnant

Warnings and precautions

Tell your doctor or health care provider before given the injection.

Special care should be taken with **HYDROCORTISONE CREAM GLENMARK:**

- If you are applying **HYDROCORTISONE CREAM GLENMARK** over a large surface area (part of your body), as systemic absorption (absorption through the skin into the bloodstream) may occur
- If you are using occlusive dressings (plasters or bandages) over the area of application
- If irritation develops on the area being treated
- If skin infections develop
- If you are younger than 18 years old (safety in children has not been established)
- If you are 65 years old or older

Other medicines and HYDROCORTISONE CREAM GLENMARK

Always tell your healthcare provider if you are using other medication, if you have recently used or plan to use any other medicines. This includes all complementary or traditional medicines.

Pregnancy, breastfeeding and fertility

Pregnancy:

Do not use **HYDROCORTISONE CREAM GLENMARK** if are pregnant, think that you may be pregnant or want to become pregnant, as it may harm your unborn baby.

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If you are pregnant or planning a pregnancy it is very important that you discuss this with your doctor before you receive any treatment. If you get pregnant during your treatment, you must immediately inform your doctor.

Breastfeeding:

You must not breastfeed your baby while you are using **HYDROCORTISONE CREAM GLENMARK**.

Driving and using machines

It is not always possible to predict to what extent **HYDROCORTISONE CREAM GLENMARK** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HYDROCORTISONE CREAM GLENMARK** affects them.

3. How to use HYDROCORTISONE CREAM GLENMARK

HYDROCORTISONE CREAM GLENMARK should be applied topically to the affected area as a thin film two or three times daily depending on the severity of the condition.

Your doctor will tell you how long your treatment with **HYDROCORTISONE CREAM GLENMARK** will last. Do not stop early, because this can cause your symptoms to return.

If you have the impression that the effect of **HYDROCORTISONE CREAM GLENMARK** is too strong or too weak, tell your doctor or pharmacist.

If you take more HYDROCORTISONE CREAM GLENMARK than you should

Topically applied **HYDROCORTISONE CREAM GLENMARK** can be absorbed in sufficient amounts to produce systemic effects.

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

If you forget to use HYDROCORTISONE CREAM GLENMARK

If you forgot to use **HYDROCORTISONE CREAM GLENMARK**, use it as soon as you remember.

Do not use double doses to make up for forgotten individual doses.

4. Possible side effects

HYDROCORTISONE CREAM GLENMARK can have side effects.

If any of the following happens, stop using **HYDROCORTISONE CREAM GLENMARK** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity reactions, such as swelling of the mouth and throat and difficulty to breathe

These are all very serious side effects. If you have them, you may have had a serious reaction to **HYDROCORTISONE CREAM GLENMARK**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice the following:

- Gastrointestinal disorder
- Infections (both secondary infections on the administration site and other body infections such as fungal infections)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stinging at the site of application
- Eczema (dry, flaky, red or irritated skin)
- Burning skin

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- Pruritus (an itching sensation on the skin)
- Rash
- Maculopapular rash (flat or raised lesions on your skin)
- Dry skin
- Folliculitis (inflammation of the hair follicles)
- Hypertrichosis (excessive hair growth)
- Acneiform eruptions (pimples resembling acne)
- Hypopigmentation (skin patches that are lighter in colour)
- Perioral dermatitis (inflammatory rash on the skin around the mouth)
- Allergic contact dermatitis (skin rash caused by contact with a substance)
- Maceration of skin (skin that is in contact with moisture for too long, wrinkly, moist skin)
- Skin atrophy (skin cell death)
- Striae (stretchmark-like discolouration on the skin)
- Miliaria (tiny white bumps on the skin)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side effects reported for **HYDROCORTISONE CREAM GLENMARK** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HYDROCORTISONE CREAM GLENMARK**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of **HYDROCORTISONE CREAM GLENMARK**.

A handwritten signature in black ink, appearing to read 'Pillay'.

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5. How to store HYDROCORTISONE CREAM GLENMARK

For external use only. Not for ophthalmic use.

Store all medicines out of reach of children.

Store at controlled room temperature between 20-25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HYDROCORTISONE CREAM GLENMARK contains

The active ingredient is hydrocortisone valerate.

The other ingredients are citric acid monohydrate, methyl paraben, polyoxyl stearyl ether, propylene glycol, purified water, sepineo P 600, sodium lauryl sulfate, steareth-100, stearyl alcohol, white petroleum.

What HYDROCORTISONE CREAM GLENMARK looks like and contents of the pack

HYDROCORTISONE CREAM GLENMARK 20:

Pack: 15 g

A filled and crimped 15 g Aluminium tube packed in a carton along with a leaflet.

Pack: 45 g

A filled and crimped 45 g Aluminium tube packed in a carton along with a leaflet.

Pack: 60 g

A filled and crimped 60 g Aluminium tube packed in a carton along with a leaflet.

Holder of Certificate of Registration

Glenmark Pharmaceuticals South Africa (Pty) Ltd

34 Monte Carlo Crescent,

A handwritten signature in black ink that reads 'Pillay'.

1.3.2 Patient Information Leaflet
HYDROCORTISONE CREAM GLENMARK, 0.2 % (Hydrocortisone valerate,
Cream)
Date: 19 September 2023
Application number: 550072



Patient Information Leaflet

Block A, First floor,
Kyalami Park, Midrand,
1684

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Pillay