

Package leaflet: Information for the user

ECURAL® Ointment

1mg/g Ointment

Active ingredient: Mometasone furoate (Ph.Eur.)

Read the entire package leaflet carefully before you start using this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is ECURAL Ointment and what is it used for?
2. What should you consider before using ECURAL Ointment?
3. How to use ECURAL Ointment?
4. What side effects are possible?
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1. What is ECURAL Ointment and what is it used for?

ECURAL Ointment contains the active ingredient mometasone furoate, a highly effective artificially produced form of the body's own cortisone (glucocorticoid). The ointment is for external use.

ECURAL ointment is used for the treatment of all inflammatory and itchy skin diseases that respond to external treatment with glucocorticoids, such as psoriasis, atopic dermatitis, and irritant and/or allergic contact eczema (contact dermatitis).

ECURAL ointment is a highly effective anti-inflammatory ointment.

ECURAL ointment should preferably be used for the treatment of very dry, scaly, and cracked skin conditions.

2. What should you consider before using ECURAL ointment?

- ECURAL ointment must not be used,
- if you are allergic to the active substance mometasone furoate, other corticosteroids, or any of the other ingredients of this medicine listed in section 6.
- in rosacea on the face
- in acne (acne vulgaris)
- in skin thinning (skin atrophy)
- in skin inflammation around the mouth (perioral dermatitis)
- in itching (pruritus) in the anal or genital area
- in diaper rash
- in skin infections caused by bacteria, e.g., skin or pus rashes, viruses, e.g., shingles, herpes, warts, parasites, or fungi, e.g., Candida or dermatophytes.
- in chickenpox
- in vaccination reactions

- in tuberculosis
- in syphilis
- on the eye or eyelid (the ointment should never get into the eye)
- on wounds or skin ulcers (skin ulcerations).
- Warnings and precautions

Please talk to your doctor or pharmacist before using ECURAL ointment.

- If you intend to use ECURAL ointment on large areas of the body or for a prolonged period, you must consult your doctor beforehand (see also section 3).
- Use in psoriasis must be closely monitored by a doctor.
- Avoid any contact with the eyes.

The side effects reported for orally or injected (systemically applied) corticosteroids, including impaired adrenal function, can also occur with topical application. This is especially true for infants and children.

If you experience blurred vision or other visual disturbances, contact your doctor.

- Children

ECURAL ointment should not be used in children under 6 years of age as there is insufficient clinical experience.

- Use of ECURAL ointment with other medicines

Inform your doctor or pharmacist if you are using, have recently used, or intend to use other medicines. This also applies to non-prescription and herbal or homeopathic medicines.

When treating with ECURAL ointment in the genital or anal area, the excipient white petrolatum may reduce the tear strength of latex condoms. This may impair the safety of the condoms.

- Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you are pregnant, or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy

The use of ECURAL ointment during pregnancy should only occur after consultation with your doctor.

As with all topically applied glucocorticoids, it should not be overlooked in pregnant women that the active ingredient can enter the unborn child's bloodstream and may affect the growth of the unborn child.

Breastfeeding

ECURAL ointment should only be used during breastfeeding after consulting your doctor.

ECURAL ointment should not be applied to the breast area.

Glucocorticoids are excreted into breast milk. If treatment with higher doses or over a longer period is necessary, breastfeeding should be interrupted (see also section 3).

- Driving ability and ability to operate machines

No special precautions are required.

- ECURAL ointment contains 20.0mg propylene glycol stearate per gram of ointment and may cause skin irritation.

3. How to use ECURAL ointment?

Always use this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

ECURAL ointment is intended for use on the skin.

Apply ECURAL ointment once daily.

ECURAL ointment is applied thinly to the affected skin areas.

Avoid long-term use of ECURAL ointment, i.e., do not use the ointment for more than 3 weeks.

Application on the face should not exceed a duration of 5 days.

Also avoid extensive application of ECURAL ointment, i.e., do not apply the ointment to more than 20% of the body surface.

When improvement occurs, the use of a weaker glucocorticoid is often recommended.

The so-called 'tandem therapy' is often useful, i.e., applying ECURAL ointment once a day and after 12 hours applying a suitable ointment without active ingredient.

Likewise, treatment with weekly alternation of ECURAL ointment and an ointment without active ingredient may be suitable. (See also section 2)

- Use in children over 6 years

Sufficient clinical studies on the safe use of ECURAL ointment in children are available for a duration of 3 weeks.

The use of ECURAL ointment in children should be for the shortest possible treatment period at the lowest effective dosage.

The duration of use for children over 6 years is a maximum of 3 weeks.

In children, ECURAL ointment should only be applied to small areas, i.e., on less than 10% of the body surface.

Please talk to your doctor or pharmacist if you have the impression that the effect of ECURAL ointment is too strong or too weak.

- If you have applied more ECURAL ointment than you should have

Inform your doctor immediately.

If ECURAL ointment has been accidentally ingested or applied in too large quantities or over too long a period, it can lead to certain conditions (e.g., Cushing's syndrome) that need to be treated.

The active ingredient content in each package is so low that in the unlikely event of accidental ingestion, it has little or no harmful effect.

- If you forget to apply ECURAL ointment

Do not apply a double amount if you have forgotten the previous application. Make up for the missed application as soon as possible and then continue with your usual application rhythm.

If you have further questions about the use of this medicine, ask your doctor or pharmacist.

4. What side effects are possible?

Like all medicines, this medicine can have side effects, but they do not have to occur in everyone.

The following categories are used for the frequency of side effects:

Very common: more than 1 in 10 treated
Common: 1 to 10 in 100 treated
Occasionally: 1 to 10 treated out of 1,000
Rare: 1 to 10 treated out of 10,000
Very rare: less than 1 treated out of 10,000
Not known: Frequency cannot be estimated from the available data

Tingling and stinging frequently occurred.

Occasionally, raised nodules (papule formation) and pustules occurred.

Very rarely, folliculitis, burning sensation, and skin itching (pruritus) occurred.

For the following side effects, the frequency is not known:

Infection, boil, sensory disturbance (paresthesia), eczema (contact dermatitis), Skin discoloration (hypopigmentation), excessive hair growth (hypertrichosis), skin striae formation, acne-like skin inflammation (acneiform dermatitis), thinning of the skin (skin atrophy), and pain or reactions at the application site.

Blurred vision occurred with the use of glucocorticoids (frequency: not known).

The following side effects occasionally occurred with the use of topical glucocorticoids and may also occur with ECURAL:

Dry skin, skin irritation, skin inflammation (dermatitis), facial skin inflammation (perioral dermatitis), skin maceration, sweat gland rash (miliaria), dilation of skin vessels (telangiectasia), and secondary infections.

It may happen that glucocorticoids alter the appearance of conditions and thus make their recognition more difficult.

Glucocorticoids can also delay the healing process.

- What should be considered in children?

Children are particularly at risk when treated with glucocorticoids to develop side effects (e.g., suppression of the hypothalamic-pituitary-adrenal axis, Cushing's syndrome).

Long-term treatment with corticosteroids can affect the growth and development of children.

- Reporting side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ECURAL ointment?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the carton or tube after 'Use by'. The expiry date refers to the last day of that month.

- Storage conditions

Do not store above 25 °C.

Do not freeze.

- Note on shelf life after opening

After opening, ECURAL ointment is stable for 4 weeks and should not be used thereafter.

Never dispose of medicines via wastewater (e.g., do not dispose of via the toilet or sink). Ask your pharmacist how to dispose of the medicine if you no longer use it. This helps protect the environment.

For more information, see www.bfarm.de/arzneimittelentsorgung.

6. Contents of the package and further information

- What ECURAL ointment contains

The active ingredient is mometasone furoate (Ph.Eur.).

1g ointment contains 1mg mometasone furoate (Ph.Eur.).

The other ingredients are: white petrolatum; 2-methylpentane-2,4-diol; bleached wax; purified water; propylene glycol stearate; phosphoric acid 10%.

- What ECURAL ointment looks like and contents of the package

ECURAL ointment is a colorless ointment.

ECURAL ointment is available in packages of 10g, 20g, 25g, 50g, and 100g ointment.

Not all package sizes may be marketed. Pharmaceutical entrepreneur and manufacturer

- Pharmaceutical entrepreneur

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This package leaflet was last revised in April 2020.

Do you have any further questions?

Please contact:

MSD Infocenter:

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E-Mail: email@msd.de

You can also find this package leaflet in formats for the blind and visually impaired at the PatientenInfo-Service <http://www.patienteninfo-service.de/>.

Transtoyou