

Package leaflet: Information for the user

ECURAL® Ointment

1mg/g cream

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 stated in this package leaflet

1. What is ECURAL fatty ointment and what is it used for?
2. What should you consider before using ECURAL fatty ointment?
3. How is ECURAL fatty ointment to be used?
4. What side effects are possible?
5. How is ECURAL fatty ointment to be stored?
6. Contents of the package and further information

1. What is ECURAL fatty cream and what is it used for?

ECURAL fatty cream contains as active ingredient mometasone furoate, a highly effective artificially produced form of the body's own cortisone (glucocorticoid). The cream is for external use. ECURAL fatty cream 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 fatty cream is a highly effective anti-inflammatory cream.

2. What should you consider before using ECURAL fatty cream?

- ECURAL fatty cream must not be used
- if you are allergic to the active ingredient mometasone furoate, other corticosteroids, soy, peanut, or any of the other ingredients listed in section 6.

mentioned other components of this medicine.

- in case of rosacea on the face
- in case of acne (acne vulgaris)
- in case of skin thinning (skin atrophy)
- in case of skin inflammation around the mouth (perioral dermatitis)
- in itching (pruritus) in the anal or genital area
- in case of 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 case of chickenpox
- in case of vaccination reactions
- in case of tuberculosis
- in case of syphilis
- on the eye or eyelid (the cream should not 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 want to apply ECURAL ointment on large areas of the body or over a longer period, you must consult your doctor beforehand (see also section 3).
- Application for 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 applies especially to infants and children. Children. If you experience blurred vision or other visual disturbances, contact your doctor. Children
- Children
Use of ECURAL ointment with other medications
- Use of ECURAL fatty ointment together with other medicinal products

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. I am sorry, but the text you provided is incomplete. Could you please provide the full text for translation?

When treating with ECURAL fatty ointment in the genital or anal area, the excipient white petrolatum may reduce the tensile 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, consult your doctor or pharmacist before using this medicine.

Pregnancy and breastfeeding

The use of ECURAL fatty 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 bloodstream of the unborn child and may affect the growth of the unborn child.

Breastfeeding

ECURAL fatty ointment should only be used during breastfeeding after consultation with your doctor. ECURAL fatty ointment should not be applied to the breast area.

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

- Driving ability and ability to operate machines

There are no special precautions required.

3. How is ECURAL fatty cream to be used?

Always use this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure. ECURAL fatty cream is intended for use on the skin.

Apply ECURAL fatty cream once daily.

ECURAL fatty cream is applied thinly to the affected skin areas.

Avoid long-term use of ECURAL fatty cream, i.e., do not use the fatty cream longer than 3 weeks.

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

Avoid extensive application of ECURAL fatty cream, i.e., do not apply the fatty cream to more than 20% of the body surface. Upon improvement, the use of a weaker glucocorticoid is often recommended.

Often the so-called "tandem therapy" is useful, i.e., h. per day. Also, a treatment alternating weekly between ECURAL fatty cream and a cream without active ingredient may be suitable. (See also section Similarly, treatment with a weekly alternation of ECURAL fatty ointment and a cream without active ingredient may be appropriate. (See also section Application in children over 2 years

- Use in children over 2 years

Sufficient clinical studies on the safe use of ECURAL fatty ointment in children are available for a duration of 3 weeks. The use of ECURAL fatty ointment in children should be as short as possible the treatment period at

the lowest possible effective dosage. The duration of use is for Children In children, ECURAL fatty cream should only be applied to small areas, i.e., on less

In children, ECURAL Fat Cream should only be applied to small areas, i.e., on less than 10% of the body surface. Please talk to your doctor become.

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

- If you have applied a larger amount of ECURAL fatty ointment than you should have

Inform your doctor immediately.

If ECURAL fatty ointment has been ingested accidentally or 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 fatty ointment

Do not apply double the amount if you have forgotten the previous application. Make up for the missed application as soon as possible and then continue with your regular application schedule. If you have further questions about the use of this medicine, please contact

If you have any further questions about the use of this medicine, please contact consult your doctor or pharmacist.

4. What side effects are possible?

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

The frequency of side effects is classified as follows: the following categories are used:

Very common: more than 1 in 10 treated

Common: 1 to 10 in 100 treated

Occasionally: 1 to 10 in 1,000 treated

Rare: 1 to 10 in 10,000 treated

Very rare: less than 1 treated out of 10,000

Not known: Frequency cannot be estimated from the available data

Tingling and stinging occurred frequently.

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

Very rarely, hair follicle inflammations (folliculitis), burning sensation and skin itching (pruritus) occurred. For the following side effects the frequency is not known:

Infection, boil, abnormal sensation (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). oedema (Frequency: Not known).

tion on the face (perioral dermatitis), rash on the face (perioral dermatitis),

Softening of the skin (skin maceration), sweat gland rash (miliaria), dilation of skin vessels (telangiectasia), and secondary infections (secondary infections).

Glucocorticoids can alter the appearance of disease symptoms and thus make their recognition more difficult. Glucocorticoids can also delay the healing process.

Other possible side effects: Hydrogenated phospholipids from soybeans can very rarely cause allergic reactions.

Other possible side effects: Hydrogenated phospholipids from soybeans can very rarely cause allergic reactions to consider in children?

- Children are particularly at risk of developing side effects (e.g., suppression of the

Children Cushing's syndrome) under treatment with glucocorticoids. Long-term treatment with corticosteroids can affect the growth and development Hypothalamic-pituitary-adrenal axis, children.

Reporting of side effects If you notice any side effects, contact your doctor or Have children.

- Reporting of side effects

If you notice any side effects, contact your doctor or Pharmacist. This also applies to side effects not listed in this package leaflet. are. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. 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 fatty cream?

Keep this medicine out of the reach of children. inaccessible. the tube after "Use by". The expiry date refers to the last day of the specified month. Storage conditions Do not store above 25 °C.

- Note on shelf life after opening

Do not store above 25 °C.

- Note on shelf life after opening

After opening is ECURAL fatty cream is stable for 3 months and should not be used thereafter. Do not dispose of medications in wastewater. Ask your pharmacist or your local waste disposal company how to dispose of the medication if you no longer need it. This helps protect the environment.

6. Contents of the package and further information

- What ECURAL fatty cream contains

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

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

The other ingredients are: white petrolatum; bleached wax; poly{O-[hydrogen-(oct-1-en-1yl)succinyl]starch}, aluminum salt; titanium dioxide; hydrogenated phospholipids from soybeans; phosphoric acid 10%; purified water; 2-methylpentane-2,4-diol.

- What ECURAL fatty cream looks like and contents of the

package

ECURAL fatty cream is a white cream. ECURAL fatty cream is available in packages of 10 g, 20 g, 25 g, 50 g, and 100 g cream. It is possible that not all pack sizes will be marketed. e not all pack sizes will be marketed.

- Pharmaceutical entrepreneur and manufacturer

Pharmaceutical entrepreneur
MSD SHARP & DOHME GMBH
Lindenplatz 1
85540 Haar
Postal address:
P.O. Box 1202
85530 Haar
Tel.: 0800/673673673
Fax: 0800/673673329
E-Mail: e-mail@msd.de

Co-distributor:
DIECKMANN ARZNEIMITTEL GMBH, 85530 Haar

Manufacturer
Schering-Plough Labo N.V.
Industriepark 30
2220 Heist-op-den-Berg
Belgium

This package leaflet was last revised in August 2017.

Do you have further questions?

Please contact:

MSD Infocenter:

Tel.: 0800/673673673

Fax: 0800/673673329 Email: 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/>.