

## Package leaflet: Information for the user

### ECURAL® Solution

1mg/g solution for application on the skin

Active substance: 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 solution and what is it used for?
2. What should you consider before using ECURAL solution?
3. How to use ECURAL solution?
4. What side effects are possible?
5. How to store ECURAL solution?
6. Contents of the pack and other information

#### 1. What is ECURAL solution and what is it used for?

ECURAL solution contains the active ingredient mometasone furoate, a potent synthetic form of the body's own cortisone (glucocorticoid). The solution is for external use.

ECURAL solution is used to treat inflammatory and itchy skin conditions of the hairy scalp, such as a form of psoriasis (psoriasis vulgaris).

ECURAL solution is a potent anti-inflammatory solution.

#### 2. What should you consider before using ECURAL solution?

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

- If you intend to use ECURAL solution 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 solution should not be used in children under 6 years of age as there is insufficient clinical experience.

- Use of ECURAL solution 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.

- 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 solution 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 solution should only be used during breastfeeding after consulting your doctor.

ECURAL solution 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).

- Ability to drive and use machines

No special precautions are necessary.

- ECURAL solution contains 300.0mg propylene glycol per milliliter of solution and may cause skin irritation.

### 3. How to use ECURAL solution?

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

ECURAL solution is intended for use on the skin.

Apply ECURAL solution once daily. A few drops of ECURAL solution are applied to the affected skin areas. Avoid long-term use of ECURAL solution, i.e., do not use the solution for more than 3 weeks.

Also avoid large-scale application of ECURAL solution, i.e., do not apply the solution to more than 20% of the body surface. When improvement occurs, the use of a weaker glucocorticoid is often recommended.

- Use in children over 6 years

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

The use of ECURAL solution 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 solution 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 feel that the effect of ECURAL solution is too strong or too weak.

- If you have used more ECURAL solution than you should

Inform your doctor immediately.

If ECURAL solution was accidentally ingested or used 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 use ECURAL solution

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 resume 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 cause side effects, although not everybody gets them. 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

Occasional: 1 to 10 in 1,000 treated

Rare: 1 to 10 in 10,000 treated

Very rare: less than 1 in 10,000 treated

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 inflammation (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 (striae), 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: unknown).

The following side effects occurred occasionally 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.

Glucocorticoids may alter the appearance of diseases, making them harder to recognize. Glucocorticoids can also delay the healing process.

- What should be considered in children?

Children are particularly at risk of developing side effects (e.g., suppression of the hypothalamic-pituitary-adrenal axis) under glucocorticoid treatment.

Cushing's syndrome) to develop. Long-term treatment with corticosteroids can affect the growth and development of 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 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](http://www.bfarm.de). By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store ECURAL solution?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the carton or bottle 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 solution is stable for 3 months and should not be used thereafter. Never dispose of medicines via wastewater (e.g., not via the toilet or sink). Ask your pharmacist how to dispose of medicines you no longer use. This helps protect the environment. For more information, see [www.bfarm.de/azneimittelentsorgung](http://www.bfarm.de/azneimittelentsorgung).

#### 6. Contents of the package and further information

- What ECURAL solution contains

The active ingredient is Mometasone furoate (Ph.Eur.). 1g solution for application on the skin contains 1mg Mometasone furoate (Ph.Eur.).

The other ingredients are: 2-Propanol (Ph.Eur.); Propylene glycol; purified water; Sodium dihydrogen phosphate 1 H<sub>2</sub>O; Hypromellose; Phosphoric acid 10%.

- What ECURAL solution looks like and contents of the package

ECURAL solution is a colorless solution. ECURAL solution is available in packages with 20ml, 50ml, and 100ml solution for application on the skin. Not all pack sizes may 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.: 0800/673 673 673  
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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 April 2020.

Do you have any further questions? Please contact:

MSD Infocenter:  
Tel.: 0800/673 673 673  
Fax: 0800/673 673 329  
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/>.