

PATIENT INFORMATION LEAFLET

CODERMO® 0,1% Cream

Topical use

- **Active substance:** Each 1 gram of cream contains 1 mg mometasone furoate.
- **Excipients:** Hexylene glycol, propylene glycol stearate, stearyl alcohol and steareth-20 mixture, Aluminium starch octenylsuccinate, white wax, white petrolatum, titanium dioxide, deionized water, phosphoric acid.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital*
- *Strictly follow these instructions. Do not take **lower or higher** doses than the recommended dose*

In this patient information leaflet:

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- 2. What you need to know before you use CODERMO®**
- 3. How to use CODERMO®?**
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1. What CODERMO® is and what it is used for?

CODERMO® is Available in tubes containing 30 gram cream. It is a white colored, homogenous cream with a characteristic odor.

CODERMO® is a cortisone-type hormone drug prepared for topical use. It is classified as a “potent corticosteroid”. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

CODERMO® is used for the treatment of psoriasis, atopic dermatitis, and certain inflammatory skin diseases due to irritants and/or responsive to mometasone furoate such as allergic dermatitis.

Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body. Dermatitis is a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy.

2. What you need to know before you use CODERMO®

DO NOT USE CODERMO® if you have any of the following

If;

- You are allergic (hypersensitive) to mometasone furoate, any of the other ingredients of this medicine or to other topical corticosteroids.
- Inflammatory wounds around the mouth
- Skin reactions following vaccination
- Varicella
- Herpes
- skin diseases around the eyes
- Inflammatory skin diseases in general
- Rosacea (a skin condition affecting the face)
- Acne
- Dermatitis around the mouth
- Genital itching
- Nappy rash
- Shingles
- Other skin infections
- Widespread plaque psoriasis

Take special care with CODERMO® if you have any of the following

- If your skin becomes irritated or sensitive after using CODERMO®, you should stop using it and start necessary treatment.
- If infection develops during treatment, your doctor will initiate an appropriate antifungal (drugs used for the treatment of fungi) or antibacterial medication therapy.
- Local or systemic toxic effects may be seen especially in cases of long-term treatment and closed dressing applied to large damaged skin surfaces or areas of skin in contact with each other.
- When potent corticosteroids are absorbed into bloodstream, they may cause symptoms of Cushing syndrome (hormonal symptoms) that disappear following discontinuation of treatment, rise in blood sugar and presence of sugar in urine.

Please consult your doctor if these warnings apply to you even at any time in the past.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

CODERMO® should not be used in pregnant women unless strictly necessary.

If you notice that you have been pregnant during treatment, consult immediately your doctor or pharmacist.

Lactation

Before using this medicine, consult your doctor or pharmacist.

CODERMO® should be used during lactation.

Driving and using machinery

CODERMO® has no effect on your ability to drive or use machines.

Important information on some excipients present in CODERMO®

CODERMO® contains stearyl alcohol that may cause local skin reactions, e.g. contact dermatitis and propylene glycol stearate that may cause irritation on the skin.

Taking with other medicines

CODERMO® has no known interaction with other medicines.

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How to use CODERMO®?**Instructions for proper use and dosage/administration frequency:**

Apply to the affected area of skin once a day.

Do not use CODERMO® on large surfaces of skin or on surfaces in contact with each other (e.g. inguinal region, armpit) for a long time, unless otherwise recommended by your doctor. Do not cover the treated areas with a bandage or any other dressing. Do not suddenly stop using the cream. Do not use around your eyes.

Do not use CODERMO® on your face for more than 5 days.

Do not use a large amount of cream on large areas of the body for a long time.

Route and method of administration:

Apply a thin layer of cream on the affected areas of skin. Then rub gently until the drug disappears.

Special use:

In children: Use in infants and young children unless absolutely necessary is not recommended. CODERMO® is not recommended in children under 2 years of age. Children may be more susceptible than adult patients to hypothalamic pituitary adrenal (HPA) axis suppression and Cushing's syndrome (an adrenal gland disorder leading to weight gain, rounded face and high blood pressure) caused by topical steroids because they have a larger skin surface area to body weight ratio.

In children, corticosteroids applied to the skin should be limited to the minimum amount that will ensure that treatment is effective. Chronic corticosteroid therapy is important for children's growth and may affect its development.

Use in the elderly:

No dosage adjustment is required.

Kidney/Liver failure

No special use.

If you use more CODERMO® than you should

Always use CODERMO® as your doctor has told you.

If you use more CODERMO® than was prescribed, tell your doctor immediately.

If you forget to use CODERMO®

If you forget to use CODERMO® at the right time, use it as soon as you remember, then carry on as before.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking CODERMO®

If you have been using CODERMO® for a long time and your skin problem seems to have got better, you should not suddenly stop using the cream. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor as he will gradually reduce how often you need to use the cream until you stop treatment altogether.

4. Possible side effects?

Like all medicines, CODERMO® may cause side effects in patients sensitive to its ingredients.

Side effects are classified in categories as shown below:

Very common	: in at least 1 patient of 10.
Common	: in less than 1 of 10 patients and more than 1 of 100 patients.
Uncommon	: in less than 1 of 100 patients but, more than 1 of 1000 patients.
Rare	: in less than 1 of 1000 patients but more than 1 of 10.000 patients.
Very rare	: in less than 1 of 10.000 patients.
Unknown	: Cannot be estimated based on available data

Very Rare;

- Inflammation of the hair follicles (ringworm)
- Burning sensation
- Itching

Unknown;

- Allergic skin reactions
- Bacterial and secondary skin infections
- Acne
- Infection in hair follicles
- Skin thinning
- Rash-like red spots
- Skin discoloration
- Stinging sensation
- Tingling
- Skin softening and stretch marks
- Skin softening and cracks
- Blurred vision
- Pain at the application area
- Reactions at the application area

Other rare local side effects that may occur with topical corticosteroids are irritation, body hair growth (hypertrichosis), loss of skin color (hypopigmentation), the darker color around the mouth (perioral pigmentation), allergic contact dermatitis, softening of the skin, secondary infection, cracks (striae), and the rash caused by perspiration.

If you experience any side effects that are not listed in this leaflet, tell this to your doctor or pharmacist.

Reporting side affects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to use CODERMO®?

*Store CODERMO® in its original packaging and keep out of the reach and sight of children.
Store at room temperature, below 25°C. Do not freeze.*

Use in compliance with the expiry date.

Do not use CODERMO® after the expiry date which is stated on the packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:

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