

PATIENT INFORMATION LEAFLET

CODERMO[®] %0.1 Lotion

Topical application

- **Active substance:** One gram lotion has 1 mg mometasone furoate.
- **Excipients:** Isopropyl alcohol, propylene glycol, hydroxypropyl cellulose, monobasic sodium phosphate dihydrate, phosphoric acid, deionized water

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

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Inform your doctor that you are taking this medicine if you seek medical attention from a doctor or healthy facility.*
- *Follow these instructions carefully. Do not take **lower or higher** doses than recommended.*

What is in this leaflet?

1. *What is CODERMO[®] and what is it used for?*
2. *What you need to know before you take CODERMO[®]*
3. *How to take CODERMO[®]?*
4. *Possible side effects?*
5. *How to store CODERMO[®]*

1. What is CODERMO[®] and what is it used for?

CODERMO[®] is presented in 30 ml plastic bottle that contains solution. They are look like colorless and clear solution.

CODERMO[®] is a cortisone type hormone medicine that is prepared for using by dripping to skin. It is located in strong corticosteroid class.

This medicines is put to use over the surface of skin on the purpose of decreasing redness and itch originated from specific skin problems.

CODERMO[®] is used in the treatment of psoriasis, atopic dermatitis, some inflammatory dermatologic diseases that respond to mometasone furoate like allergic dermatitis that is dependent on corrosive materials in order to annihilate inflammation symptom.

Psoriasis is a skin disease that is seen in elbows, knees, hairy scalp and different areas of the body. Dermatitis is a disease that shows up because of reacting against exogeneous agents (for instance, washing agents), and that cause to redness and itch over skin.

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

Do not take CODERMO®

If;

- If you are highly allergic to mometasone furoate or any auxiliary product in this medicine and other topical corticosteroids
- In inflammatory wound around mouth
- In skin reaction after vaccine
- Chickenpox
- Herpes
- In skin disease around supraorbital
- In general inflammatory skin disease

CARE SHOULD BE EXERCISED when using CODERMO® in the following conditions

If;

- If irritation and sensitiveness develops during treatment, using CODERMO® should be stopped, and it should be started to required treatments.
- If an infection develops during treatment, your doctor has you start to a proper antifungal (the medicine used in fungal treatment) or antibacterial medication.
- Especially in damaged extensive skin surfaces or in the long-term treatments maintained in touched one another skin areas or in closed medical dressing implementations may be seen local and systematic toxic effects.
- Mixing to blood of strong topical corticosteroids may cause to Cushing syndrome symptoms (hormonal symptoms) disappeared after giving up treatment, to rising of the blood sugar level, and to finding glycosuria.
- The minimum dose that provides desired effect in children should be used. The long-term corticosteroid treatment may affects growth in children.

If these warnings apply or have ever applied to you, please discuss with your doctor.

Pregnancy

Please ask your doctor or pharmacist before taking this medicine.

CODERMO® should not be used in pregnant women as long as it is not necessary.

Tell your doctor immediately if you are pregnant or planning to become pregnant; he/she will decide if you should take CODERMO®

Breastfeeding

Please ask your doctor or pharmacist before taking this medicine.

It should not be used in nursing period.

Driving and using machines

CODERMO® does not affect your vehicle or machine usage skills.

Important informations about some of the ingredients of CODERMO®

Propylene glycol in the content of CODERMO® may cause to irritation in skin.

Other medicines and CODERMO®

Known interaction with other medicines of CODERMO® does not have.

If are using any medicine with prescription or nonprescription now, or if you have used recently, please give information about them to your doctor or pharmacist.

3. How to take CODERMO®?

Instructions for appropriate use and dose/administration frequency:

Apply to disease skin once a day.

Do not use long time CODERMO® in the surface of wide or contacted to one another skin (such as groin, armpit area) as long as your doctor does not suggest. Do not close skin area that is treated with bandage or any other dressing. Do not give up your treatment immediately. Do not contact lotion to your eyes.

Do not apply CODERMO® to your face more than 5 days.

Do not use more than 5 days in children.

Avoid from using in large amount.

Route and method of administration

Approach the mouth of the bottle to diseased skin area. Drip CODERMO® to diseased skin some, and then massage softly until medicine disappears.

Special usage conditions:

Usage in children: If your doctor does not recommend, do not use in children below 2 years old.

Usage of topical corticosteroids in children should limit with lowest amount that provides medicine effective. Chronic corticosteroid treatment may affect children growth and development.

If you have an impression that the effect of CODERMO® is too weak or too strong, talk to your doctor or pharmacist.

If you have taken more CODERMO® than you should:

You can use the CODERMO® as recommended by your doctor.

Talk to your doctor or pharmacist if you have taken more CODERMO® than you should.

If you forget to take CODERMO®

If you forget to use CODERMO®, use immediately after you remember, and then continue to your medicine averagely.

*Do not take a double dose to make up for a forgotten dose.*⁴

Side effects that may occur when CODERMO® treatment is stopped

If you are using CODERMO® for a long time, and your skin disease recovers, give up using lotion immediately. If you give up immediately, you may notice that your skin becomes red, and feel sting and burning. In order to prevent this, please talk to your doctor; your doctor will reduce your lotion usage frequency gradually until he/she stop treatment completely.

4. Possible side effects?

Like all medicines, side effects may occur in people who is sensitive to substances that have in content of CODERMO®. Especially, when CODERMO® is implemented, it may cause to burning or irritation feel; if irritation is realized during implementation, CODERMO® usage should be terminated.

Side effects are categorized like shown in the categories below;

Very common: may affect more than 1 user in 10

Common : may affect 1 to 10 users in 100

Uncommon : may occur in less than 1 patient in 100 but more than 1 patient in 1000

Rare : may occur in less than 1 patient in 1000 but more than 1 patient in 10000

Very rare : may occur in less than 1 patient in 10000

Not known : frequency cannot be estimated from available data

Rare;

- Fluffy lesion in skin
- Fluffy purulent lesion in skin
- Pricking in skin

Very rare;

- Burning
- Folliculitis
- Reaction resembled acne
- Itching
- Thinning in skin

The local undesirable effects that are notified as rare during other topical corticosteroid treatments; irritation, civilization (hypertrichosis), color fading in skin (hypopigmentation), becoming darker around mount (perioral pigmentation), allergic contact dermatitis, softening in skin, secondary infection, crack (stria), and eruption that shows up depending upon swelter.

You should also inform your doctor or pharmacist if you get any side effects not listed in these instructions.

Reporting of side effects

If you experience any side effects listed or not listed in this leaflet, talk to your doctor, pharmacist, or nurse. Also, you can report the side effects to TUFAM (Turkish Pharmacovigilance Center) by calling at 0 800 314 00 08 or by clicking the “Drug Side Effect Reporting” icon at www.titck.gov.tr. By reporting these side effects, you will help collecting more information on the safety of this medicine.

5. How to store CODERMO®

Keep CODERMO® in the place that children can not see, reach and in its package.
Store at room temperature below 30°C, and do not frost it.

Use it according to its expiration date.

Do not use CODERMO® after the expiration date in package.

Medicines should be thrown away through waste water or household garbage. Please ask to your pharmacist how you should throw away medicines that are not necessary anymore. This precaution will help in protection of the environment.

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