

PATIENT INFORMATION LEAFLET

KLOBATE 0.05% cream **For topical use.**

Active substance(s): 0.05% clobetasol contains 17-propionate.

Excipient(s): Stearyl alcohol, propylene glycol, vaseline, sorbitan sesquioleate, disodium EDTA, polysorbate 80, chlorocresol and deionized water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

- 1. What KLOBATE is and what it is used for**
- 2. Before you use KLOBATE**
- 3. How to use KLOBATE**
- 4. Possible side effects**
- 5. How to store KLOBATE**

1. What KLOBATE is and what it is used for?

KLOBATE belongs to a drug group called topical steroids and applied to the skin. Topical steroids reduce itching and redness in certain skin problems.

KLOBATE is used to reduce inflammation in skin problems such as discoid lupus erythematosus (plaques usually seen in the face - a kind of skin disease), lichen planus (a benign skin disease affecting the skin, skin appendages and mucous membranes), psoriasis and refractory eczema.

2. Before you use KLOBATE

Do not use KLOBATE in the following conditions

If;

- you have an untreated skin infection,
- you have acne rosacea (severe flushing of skin on and around your nose) or perioral dermatitis (spotty red rash around your mouth),
- you have allergy (hypersensitivity) to clobetasol propionate or any ingredients of KLOBATE
- you have itching without inflammation,
- the affected area will be covered with a bandage or diaper,
- you have itching around your back passage or private parts,

- you have viral skin infections (e.g. herpes, chickenpox),
- you have skin lesions caused by fungi or other microbes,
- children under 1 year old.

TAKE SPECIAL CARE WITH KLOBATE in the following conditions

- Do not apply the cream to the skin on your face as the skin on your face thins easily unless your doctor recommends
- Do not let the cream get into your eyes. If it does, wash it out with plenty of water.
- Do not use for a long time. If you do not have any improvement after four weeks, tell your doctor.
- If you are breastfeeding,
- If you are pregnant or planning to become pregnant,
- Treatment should not exceed 5 days when applied in children and on the face and do not cover the treated area with a dressing,
- Psoriasis treatment should be monitored closely.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using KLOBATE with food and drink

No data available.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

KLOBATE should be used in the lowest amount for the minimum time period during pregnancy.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking the medicine.

It is not known whether KLOBATE pass into the breast milk. Because many drugs pass into the breast milk, KLOBATE should be used with caution in lactating women. It should not be applied to the breast to prevent accidental ingestion by the baby during breastfeeding.

Effects on ability to drive and use machines

No effect is expected.

Important information about some of the ingredients of KLOBATE

It contains propylene glycol which may cause skin irritation. Also, stearyl alcohol may cause local skin reactions (e.g. allergic contact skin disease)

Using with other medicines

Tell your doctor if you are using ritonavir (a drug used to treat HIV infection) or itraconazole (a drug used to treat fungal infections).

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use KLOBATE?

Instructions for appropriate method and dose/frequency of administration:

If you do not understand or have any difficulties, consult your doctor or pharmacist.

It is gently applied in a thin layer in the amount that will cover the affected area until recovery is achieved once or twice a day over a period of 4 weeks. Then, the frequency of administration is reduced or the treatment is replaced by a less potent drug. Sufficient time should be waited for absorption before an emollient is applied after each administration

Treatment and diagnosis should be re-evaluated if the condition worsens or if improvement is not achieved within 2-4 weeks.

Unless your doctor tells;

- Do not use more than mentioned above,
- Do not use for prolonged periods of time on large body surfaces (e.g. almost every day for weeks or months),
- When applied to the face, it should be used for not more than 5 days.

Always use the cream exactly as your doctor has told you. The patient information leaflet tells you what dose and how often you take your medicine. Ask your doctor or pharmacist if you are not sure.

Route and method of administration:

KLOBATE is applied only on the skin. After clobetasol propionate administration, if your hands are not the treated area, you should wash your hands.

Different age groups:

Use in children:

It should not be used in children under one year old. Treatment should not exceed 5 days when applied in children and do not cover the treated area with a dressing. It should be administered in the lowest amount that it can benefit in children.

Use in elderly:

KLOBATE should be used in the lowest amount for the minimum time period to achieve the desired clinical effect.

Special populations:

Kidney/Liver failure:

KLOBATE should be used in the lowest amount for the minimum time period to achieve the desired clinical effect.

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

If you have used more KLOBATE than you should:

Although it is unlikely that high doses will be used in a short period of time, hypercortisolism (excessive secretion of steroid hormone from the adrenal gland) may occur due to prolonged high dose or misuse and in such a case, treatment with KLOBATE should be discontinued by reducing the dose because of the risk of adrenal insufficiency.

If you may have taken more KLOBATE than you should, talk to a doctor or pharmacist.

If you forget to use KLOBATE

If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

Do not use a double dose to make up for a forgotten dose.

If you stop using KLOBATE

When KLOBATE treatment is stopped, no adverse effects are expected. Nevertheless, do not stop taking medicine without consulting your doctor

4. Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of KLOBATE.

Side effects are classified as follows:

Very common: may be seen at least 1 in 10 patients

Common: may be seen less than one in 10 patients but more than one in 100 patients

Uncommon: may be seen less than one in 100 patients but more than one in 1000 patients

Rare: may be seen less than one in 1000 patients but more than one in 10.000 patients

Very rare: may be seen less than one in 10000 patients

Unknown: cannot be estimated from the available data.

Common

- Redness, rash, itching, burning allergic contact reaction at the application site

Uncommon

- Thinning of the skin with stretch marks
- Veins under the surface of your skin may become more noticeable.

Very rare

- Weight gain,
- Moon facies/rounding of the face,
- Obesity,
- Thinning of the skin,
- Wrinkle in the skin,
- Dry skin,
- Appearance of blood vessels under skin surface,
- changes in skin coloring,
- increased hair growth on the body,
- Hair loss/stopped hair growth/thinning of the hair,
- Allergic reaction at the application site,

- Worsening condition on the skin,
- Irritation at the application site,
- Redness,
- Rash, itching,
- Inflammatory swelling, if you have psoriasis,
- Skin infection,
- Weight gain / slow growth in children,
- Decrease in blood cortisole levels,
- Increased blood sugar level and presence of the sugar in the urine,
- Increased blood pressure,
- Blurred vision (cataract),
- Increase in intraocular pressure (glaucoma),
- Weakness due to mineral loss in bones (osteoporosis).

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store KLOBATE

Keep in the original package and out of the reach and sight of children.

Store in room temperature under 25°C.

Use in accordance with expiry date.

Do not use KLOBATE after the expiry date which is stated on the package.

Marketing Authorization Holder:

Talu İlaç ve Kozmetik Dağıtım ve Pazarlama Ltd. Şti.

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Manufacturer:

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This patient information leaflet was approved on 18/08/2016.