

PATIENT INFORMATION LEAFLET

PSOBETAZOL 0,05% Foam

Applied externally.

- **Active ingredient:** Contains 25 mg (0,05% w/w) clobetasol propionate (equivalent to 22 mg Clobetasol).
- **Excipients:** Isopropyl alcohol, Polysorbate, cocamidopropyl betaine, propylene glycol, macrogol (polyethylene glycol), purified water.

Before you start using this medicine, read this PATIENT INFORMATION LEAFLET carefully, because it contains important information for you.

- *Keep this leaflet. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **higher or lower** doses of the drug than the recommended dose.*

In this leaflet:

- 1. What is PSOBETAZOL and what is it used for?***
- 2. Things to consider before using PSOBETAZOL***
- 3. How to use PSOBETAZOL?***
- 4. What are the possible side effects?***
- 5. Storing condition for PSOBETAZOL***

Headings are included.

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

PSOBETAZOL is a product containing 25 mg clobetasol propionate, in the form of a colorless or yellowish clear solution, which turns into foam form with the foam pump head. It is available in 50 ml bottles with a pump head and a transparent pump cap.

PSOBETAZOL contains Clobetasol propionate which is a very powerful corticosteroid belonging to the group of topical corticosteroids.

PSOBETAZOL is applied to the skin.

PSOBETAZOL is used for the short-term treatment of scalp psoriasis that does not respond adequately to weaker corticosteroids.

2. Things to consider before using PSOBETAZOL

DO NOT USE PSOBETAZOL in the following situations

- If you are allergic to clobetasol propionate or other corticosteroids or any of the excipients contained in PSOBETAZOL,
- If you have a skin disease caused by viral (herpes, shingles, chickenpox virus, etc.), bacterial (infectious skin diseases caused by bacteria such as impetigo), fungal (microscopic fungus) or parasitic, etc.,
- Burn, ulcer wounds or rosacea (rosacea with facial redness and acne-like bumps), acne, inflammation of the skin around the mouth, itching in the anus or genital area (reproductive organs),
- Any part of your body or face (including eyelids) except the scalp,
- In children under 12 years of age.

USE PSOBETAZOL CAREFULLY in the following situations

Consult your doctor or pharmacist before using PSOBETAZOL.

In case of any allergic reaction, if redness, itching or painless tissue swelling (edema) occurs, stop taking PSOBETAZOL immediately and consult your doctor.

Like other corticosteroids which apply on skin, PSOBETAZOL can be absorbed through the skin and cause side effects such as adrenocortical suppression (a disease in which the adrenal gland is suppressed). Therefore:

- Long-term use of PSOBETAZOL should be avoided,
- PSOBETAZOL should not be applied to large surface areas on the body,
- Treated areas should not be bandaged or covered without a doctor's advice,
- It should not be used on wounds and ulcerated wounds.

With the sudden discontinuation of corticosteroids used for a long time or in large amounts, skin redness, burning and stinging may occur. This is caused by the gradual discontinuation of the drug (Rebound Phenomenon).

PLEASE TALK TO YOUR DOCTOR in the following situations.

- If there is no improvement in your condition after 2 weeks of treatment,
- If an inflammation occurs (this may require stopping PSOBETAZOL treatment),
- If you have had vision problems caused by blurred vision, glaucoma (increased intraocular pressure) or cataracts (loss of transparency of the eye lens, curtain falling on the eye).

Wash your hands after each application.

If it comes into contact with your face or eyes, wash your face and eyes with plenty of water.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Using PSOBETAZOL with food and drink

There is no data on the use of PSOBETAZOL with food and drink.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant or planning to become pregnant, consult your pharmacist or doctor before taking this medicine.

PSOBETAZOL should not be used in pregnant women without a doctor's advice.

If you realize you are pregnant during your treatment, consult your doctor immediately.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

If you are breast-feeding, consult your pharmacist or doctor before taking this medicine.

PSOBETAZOL should not be used by breastfeeding women without a doctor's advice.

Driving and using machines

PSOBETAZOL does not affect your ability to drive and use machines.

Important information about some of the ingredients in PSOBETAZOL

This medicinal product contains propylene glycol. Propylene glycol may cause skin irritation.

Use with other drugs

If you are currently using or have recently used any prescription or non-prescription medication, please inform your doctor or pharmacist about them.

3. How to use PSOBETAZOL?**Instructions for proper use and dose/frequency of administration:**

Always use PSOBETAZOL as recommended by your doctor. If you are not sure, consult your doctor or pharmacist.

Use the medicine only for the conditions prescribed. PSOBETAZOL is for scalp use only, do not swallow.

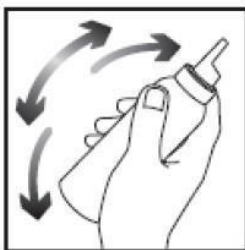
It is not recommended to spray PSOBETAZOL directly on the hand. Because the foam will start to melt as soon as it touches the hot skin.

PSOBETAZOL should be applied only to the affected areas on the scalp, twice a day, once in the morning and once in the evening.

Application route and method:

PSOBETAZOL should only be applied to the affected areas of the scalp.

1. Shake the bottle well.



2. Apply the bottle directly to the scalp or after squeezing a small amount onto the bottle cap, a plate or any cold surface, and apply it to the scalp.

Apply PSOBETAZOL in a thin layer, covering the affected areas as little as possible.

3. Remove your hair from the foam and gently massage your scalp until the foam disappears and is absorbed. Repeat if necessary to treat the entire affected area.



Do not apply PSOBETAZOL to the eyelids and avoid contact of the drug with the eyes, nose and mouth.

It is not recommended to spray PSOBETAZOL directly on the hand. Because the foam will start to melt as soon as it touches the hot skin.

After applying PSOBETAZOL, wash your hands and throw away any unused foam.

Do not use PSOBETAZOL on your face. If your eyes, nose or mouth come into contact with the foam, rinse thoroughly with cold water. You may feel a stinging sensation. If this continues, talk to your doctor.

Do not use PSOBETAZOL more than 50 grams per week.

Do not bandage or cover the spots caused by psoriasis without a doctor's advice.

Treatment should not be continued for more than 2 weeks. After this period, PSOBETAZOL can be used when necessary. Alternatively, your doctor may prescribe a weaker steroid class to keep your condition under control.

Different age groups:

Use in children:

It is not recommended for use in the childhood age group unless absolutely necessary.

Use in the elderly:

The use of PSOBETAZOL in the elderly has not been studied.

Special use cases:**Kidney/Liver Failure**

Its use in patients with renal failure and liver failure has not been studied.

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

If you use more PSOBETAZOL than you should:

If you have used PSOBETAZOL more than you should or have used it for a long time without your doctor's recommendation, inform your doctor immediately.

If you have used more PSOBETAZOL than you should, talk to a doctor or pharmacist.

If you forget to use PSOBETAZOL:

Use the forgotten dose as soon as you remember. Administer the next dose at the normal time.

If you forget to use many doses, please consult your doctor.

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

Effects that may occur when treatment with PSOBETAZOL is terminated:

Do not stop using PSOBETAZOL immediately, this may harm you. Your doctor may discontinue your treatment gradually and you may need to be checked regularly.

For further questions regarding the product, please consult your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, PSOBETAZOL may have side effects in people who are sensitive to its ingredients.

The following side effects may occur as a result of using PSOBETAZOL:

Side effects are listed as shown in the following categories:

Very common : It can be seen in at least 1 in 10 patients.

Common : It can be seen in less than 1 in 10 patients, but in more than 1 in 100 patients.

Uncommon : It can be seen in less than 1 in 100 patients, but in more than 1 in 1000 patients.

Rare : It can be seen in less than 1 in 1000 patients, but may occur in more than 1 in 10000 patients.

Very Rare : It can be seen in less than 1 in 10000 patients.

Unknown : cannot be estimated from the available data)

If one of the following occurs, stop using PSOBETAZOL and IMMEDIATELY inform your doctor or go to the emergency department of the nearest hospital.

- Hypersensitivity reactions such as regional irritation (allergic reactions such as redness, itching or painless tissue swelling (edema))

These are all very serious side effects. If you have one of these, it means you have a serious allergy to PSOBETAZOL. You may need emergency medical attention or hospitalization.

Common:

- Burning sensation
- Reactions occurring at the application area

Very Rare:

- Tingling, numbness or stinging sensation
- Eye irritation
- Veins on the skin surface become visible
- Skin irritation and sensitivity
- Itchy skin rash (contact dermatitis)
- Worsened scaly skin rash (worsening of psoriasis)
- Redness at the application area
- Itching and sometimes pain at the application area
- Presence of blood, protein and nitrogen in the urine (can be detected by a doctor)

Unknown:

- Changes in hair growth (abnormal hair growth away from the application area and in different parts of the body, hypertrichosis)
- Skin discoloration (pigmentation change)
- Irritation of the hair roots (redness at the roots of the hair and feeling of pain, warmth, folliculitis)
- Delayed healing of wounds
- Glaucoma (increased intraocular pressure), cataract (loss of transparency of the eye lens, curtain falling on the eye), blurred vision
- Facial redness and rash
- Rash around the mouth

Side effects caused by long-term use include:

- Formation of white spots (streaks) on the skin and widening of the vessels in the skin
- Long-term or excessive use of corticosteroids can cause suppression of the adrenal glands and a disease called Cushing's Syndrome (a type of hormone disease with symptoms such as weight gain, high blood pressure (hypertension), moon face appearance, facial redness, changes in urine and blood sugar) as a result of some hormonal changes
- Thinning of the skin due to long-term use of corticosteroids

Rarely, treatment of psoriasis with corticosteroids (or discontinuation of treatment) may worsen the condition and lead to the development of a pustular form of the disease. Occasionally, the scalp condition may recur upon discontinuation of treatment with corticosteroids. If PSOBETAZOL is not used according to instructions, existing inflammations may worsen.

If you experience any side effects not mentioned in this instruction manual, inform your doctor or pharmacist.

5. Storing condition for PSOBETAZOL

Keep PSOBETAZOL out of the sight and reach of children and in its package.

Store at room temperature below 25°C.

Once opened, it should be used within 2 months provided that it is stored at room temperature below 25°C.

Use in accordance with the expiration date.

Do not use PSOBETAZOL after the expiration date stated on the label or packaging.

If you notice any defects in the product and/or its packaging, do not use PSOBETAZOL.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorisation Holder:

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. Sok. No: 7/3

06520 Balgat-Çankaya/Ankara

Manufacturing Site:

Drogsan İlaçları Sanayi ve Ticaret A.Ş.

06760 Çubuk-Ankara

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