SUMMARY OF PRODUCT CHARACTERISTIC

1. NAME OF THE MEDICINAL PRODUCT

PSOBETAZOL 0,05% Foam

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Contains 25 mg of clobetasol propionate, equivalent to 22 mg of clobetasol.

Excipients:

For excipients, refer to section 6.1.

3.PHARMACEUTICAL FORM

Topical foam.

It is a foam in the form of a colorless or yellowish clear solution that turns into foam when sprayed with a pump. Each spray contains 0.2 mg of clobetasol propionate.

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

Indicated for the short-term treatment of steroid-responsive scalp dermatoses, such as psoriasis, that do not respond adequately to less potent steroids.

4.2. Posology and method of administration

Each spray contains 0.2 mg of clobetasol propionate. For use in adults.

Posology / Frequency and duration of use:

PSOBETAZOL is a potent topical corticosteroid and should therefore be limited to a maximum of 2 weeks of consecutive treatment and should not be used in quantities exceeding 50 grams per week.

Method of administration:

For external use only.

PSOBETAZOL should be applied to the affected areas twice a day. There is no data supporting its efficacy when applied once daily. The foam is designed for easy spreading without excessive liquefaction and easy application to affected areas. Apply a small amount (about the size of a walnut) directly to the lesions or onto the cap, plate, or another cool surface and spread over the lesions. Avoid contact with eyes, nose, or mouth. It is not recommended to apply to the hands since it melts immediately on warm skin. The foam should be gently massaged into the lesions until it disappears and is absorbed. Continue until the lesions have healed.
To ensure contact with each lesion, hair in the affected area should be removed.

Special populations:

Pediatric population:

Not recommended for use in children unless absolutely necessary.

Geriatric population:

No data available on the use of PSOBETAZOL in the geriatric population.

Renal/Hepatic impairment:

No data available regarding the use of PSOBETAZOL in patients with renal or hepatic impairment.

4.3. Contraindications

PSOBETAZOL is contraindicated in the following conditions:
• Hypersensitivity to clobetasol propionate, any corticosteroid, or any excipient in PSOBETAZOL (see section 6.1)
• Ulcerated lesions and burns
• Rosacea
• Acne vulgaris
• Perioral dermatitis
• Perianal and genital pruritus
PSOBETAZOL should not be used for the treatment of primary skin infections caused by parasites, viruses, fungi, or bacteria. PSOBETAZOL should not be applied to the face.

PSOBETAZOL should not be applied to the eyelids (due to the risk of glaucoma and cataracts).

4.4. Special warnings and precautions for use

Hypersensitivity (allergic reactions)

PSOBETAZOL should be used with caution in patients with a history of hypersensitivity to corticosteroids or any excipient. Local hypersensitivity reactions may resemble the symptoms of the condition being treated (see section 4.8). If any signs of hypersensitivity occur, treatment should be discontinued immediately.

Infections and infestations

PSOBETAZOL should not be used on open or ulcerated wounds. Secondary infections may develop. Occlusive dressings may create warmth and humidity, promoting bacterial infections. The skin should be cleaned before applying a new dressing. If any infection spreads, the use of topical corticosteroids should be stopped, and appropriate antimicrobial treatment should be initiated.

Adrenal suppression

Signs of hypercortisolism (Cushing's syndrome) and reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, especially in children, may result from increased systemic absorption of topical steroids.

If any of the above occurs, the frequency of application should be reduced, or a lower-potency corticosteroid should be used, and the treatment should be tapered gradually. Long-term treatment should be avoided because it may easily lead to adrenal suppression, even without occlusive dressings. Once the lesions are healed or after the maximum 2-week treatment period, a step-down approach with intermittent therapy or a lower-potency steroid should be considered.

Visual disturbances

Systemic and topical corticosteroids have been associated with visual disturbances. If a patient complains of blurred vision or other visual disturbances, they should be referred to an eye

specialist for evaluation, including rare conditions like cataracts, glaucoma, or central serous chorioretinopathy (CSCR) that may occur following the use of systemic or topical corticosteroids.

Increased systemic absorption of topical steroids

Increased systemic absorption of topical steroids can lead to systemic side effects, including adrenal suppression and immune system suppression.
Increased systemic absorption is more likely in the following situations:
• Prolonged exposure
• Application to large surface areas
• Use on occluded skin areas (e.g., intertriginous areas or with occlusive dressings)
• Application to areas with thin skin (e.g., face)
• Application to dry skin or where the skin barrier is compromised
• Increased hydration of the stratum corneum
PSOBETAZOL should not be used with occlusive dressings unless under medical supervision.

Rebound phenomenon

Discontinuing long-term corticosteroid treatment suddenly can lead to redness, burning, and stinging in the skin, known as the rebound phenomenon. This occurs due to abrupt cessation without tapering.

Topical corticosteroids can be dangerous because rebound flares may follow tolerance development. Patients may also be at risk of generalized pustular psoriasis and local or systemic toxicity due to impaired skin barrier function. Close patient monitoring is important.

Eye diseases

Systemic corticosteroid treatment is associated with the formation of glaucoma and cataracts. This risk has also been reported with local corticosteroid use, particularly on the eyelids. Additionally, long-term use of potent topical corticosteroids on the face or body has been associated with the development of glaucoma and cataracts.
The hypertensive effects of topical steroids on the eyes are temporary after stopping treatment, but defects related to glaucoma and cataracts may be permanent.

PSOBETAZOL should not be applied to the eyelids.
To avoid eye contact, patients should wash their hands after each application of PSOBETAZOL. If the product comes into contact with the eyes, rinse the affected eye(s) thoroughly with water.

Patients on long-term, potent topical corticosteroid therapy, especially those at high risk for cataracts (e.g., diabetics, smokers) or glaucoma (with a personal or family history), should have regular cataract and glaucoma screenings. PSOBETAZOL contains propylene glycol, which may cause skin irritation.

4.5. Interactions with other medicinal products and other forms of interaction
No drug interaction studies have been conducted for PSOBETAZOL.

4.6. Pregnancy and lactation

General advice

Pregnancy category: C

Women of childbearing potential / Contraception

No special contraception is required for women of childbearing potential using PSOBETAZOL. However, it should not be used for extended periods, in high doses, or in large areas in women planning to become pregnant.

Pregnancy
Corticosteroids have been shown to cause fetal developmental anomalies in animal studies (see section 5.3). There are insufficient and controlled studies on the use of clobetasol in pregnant women. Epidemiological studies suggest that oral corticosteroids carry a minimal or no risk for conditions like cleft palate. Limited data suggest that extensive use of potent topical corticosteroids like clobetasol propionate during pregnancy may pose a small risk for low birth weight.
PSOBETAZOL should not be used during pregnancy unless absolutely necessary. There is not enough data regarding the use of PSOBETAZOL in pregnant women. Studies conducted on animals have shown reproductive toxicity (see Section 5.3). The potential risk to humans is unknown.

Lactation

The safety of clobetasol propionate during breastfeeding has not been established. Glucocorticoids pass into breast milk, so PSOBETAZOL should not be used in breastfeeding women unless clearly needed.

Fertility

There is insufficient data on the effects of topical corticosteroids on fertility in humans. Animal studies have shown that subcutaneous application of high doses of clobetasol reduces fertility in female rats (see section 5.3).

4.7. Effects on ability to drive and use machines

No studies have been conducted regarding the effect of PSOBETAZOL on the ability to drive or operate machinery.

4.8. Undesirable Effects

Summary of the safety profile

As with other topical corticosteroids, prolonged use of large quantities of clobetasol propionate or treatment of extensive areas can cause adrenal suppression. In adults, this condition may be temporary if the weekly dose does not exceed 50 grams.

Prolonged and intensive treatment with a highly potent corticosteroid preparation can cause local changes such as skin atrophy, bruising secondary to skin thinning, skin fragility, telangiectasia (especially on the face), and striae, particularly affecting the proximal extremities.

Additional local adverse effects associated with glucocorticosteroids include perioral dermatitis, rosacea-like dermatitis, delayed wound healing, rebound phenomena that can lead to dependency on corticosteroids, and effects on the eyes. Known adverse effects of glucocorticosteroids include increased intraocular pressure and cataracts (see section 4.4).

The use of corticosteroids in treating psoriasis (or their withdrawal) is thought to occasionally induce the pustular form of the disease (see section 4.4).

Secondary infections may develop. Factors such as heat and moisture caused by occlusive dressings can foster bacterial infections, so the skin should be cleansed before applying a new dressing. PSOBETAZOL should be applied afterward. Improper use of the product may mask

or exacerbate bacterial, viral, parasitic, or fungal infections (see section 4.4). Folliculitis has also been reported.

Contact allergy to PSOBETAZOL or its excipients may occur. If hypersensitivity reactions arise, the product should be discontinued immediately, as symptoms may worsen.

The most common adverse effects associated with clobetasol propionate foam use include application site burning (5%) and other nonspecific reactions.

System Organ Class	Very Common	Common	Uncommon	Rare	Very Rare	Unknown
Infections and infestations				Secondary infections, folliculitis		
Endocrine disorders				Pituitary-adrenal suppression		
Nervous system disorders				Paresthesia		
Eye disorders				Eye irritation, cataracts, blurred vision		
Skin and subcutaneous disorders				Vasodilation, dermatitis (unless specified otherwise), contact dermatitis, worsening psoriasis, skin irritation, skin sensitivity, skin tightness	Pigmentation changes, hypertrichosis	
General disorders and application site conditions				Application site burning, application site reactions (unless specified otherwise)	Application site erythema, application site pruritus, pain	
Investigations				Blood in urine, increased mean cell volume, protein in urine, nitrogen in urine		

Frequency definitions:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from available data). (≥1/10,000 to <1/1,000); very rare (<1/10,000); unknown (cannot be estimated from available data).

Reporting of suspected adverse reactions:

Reporting suspected adverse drug reactions is important as it enables continuous monitoring of the benefit-risk balance of the drug. Healthcare professionals are encouraged to report any adverse reactions to the Turkish Pharmacovigilance Center (TÜFAM), via www.titck.gov.tr, email: tufam@titck.gov.tr, phone: 0 800 314 00 08, or fax: 0 312 218 35 99.

4.9. Overdose and Treatment

No overdose cases have been reported. Topically applied PSOBETAZOL may be absorbed in sufficient quantities to produce systemic effects. If symptoms of hypercortisolism occur, topical steroids should be withdrawn gradually under medical supervision to minimize the risk of acute adrenal suppression (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Corticosteroids, very potent (Group IV).
ATC Code: D07AD01

Mechanism of Action

Like other topical corticosteroids, clobetasol propionate exhibits anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanisms underlying the anti-inflammatory activities of topical steroids in corticosteroid-responsive dermatoses are not completely understood. However, it is believed that corticosteroids act by inducing proteins known as lipocortins, which inhibit the enzyme phospholipase A2. These proteins regulate the release of arachidonic acid, a precursor of potent mediators of inflammation such as prostaglandins and leukotrienes, from membrane phospholipids.

Pharmacodynamic Effects

A vasoconstrictor study demonstrated that clobetasol propionate foam has comparable potency to other clobetasol propionate formulations, based on skin blanching effects.

Clinical Efficacy and Safety

The efficacy and safety of 0,05% clobetasol propionate foam have been demonstrated in double-blind, placebo- and active-controlled (clobetasol propionate solution) studies. In clinical trials involving 188 adult participants with moderate to severe scalp psoriasis, clobetasol-

containing products were applied to the entire scalp twice daily for two weeks. Improvements in itching, scaling, erythema, and plaque thickness were observed. Complete or nearly complete resolution was seen in 74% of participants using clobetasol propionate foam, compared to 61% using clobetasol solution and 6–10% in the placebo group. Improvements persisted for two weeks after treatment cessation.

Data from pediatric and adolescent populations indicate that clobetasol propionate foam is safe and effective in treating mild to moderate plaque psoriasis in patients aged 12 years and older. A randomized, double-blind, placebo-controlled study involving 497 patients (including approximately 27% adolescents) showed that clobetasol propionate foam was four times more effective than placebo in treating mild to moderate plaque psoriasis. Adverse events were similar between adults and adolescents.

5.2.Pharmacokinetic Properties

General Characteristics

Absorption:

The degree of percutaneous absorption of topical corticosteroids is determined by several factors, including the vehicle and the integrity of the epidermal barrier. Absorption may increase under occlusion, in cases of inflammation, or with other skin conditions.

Distribution:

Once absorbed through the skin, topical corticosteroids are distributed similarly to systemically administered corticosteroids.

Biotransformation:

Topical corticosteroids absorbed through the skin are metabolized primarily in the liver, similar to systemically administered corticosteroids.

Elimination:

Corticosteroids and their metabolites are excreted via the kidneys, with some elimination through bile. A controlled pharmacokinetic study revealed reversible adrenal suppression in 3 of 13 participants treated with 0,05% clobetasol propionate foam over at least 20% of the body surface for 14 days.

5.3.Preclinical Safety Data

Non-clinical data from repeated-dose toxicity and genotoxicity studies reveal no special hazard to humans. No topical studies have been conducted to evaluate clobetasol's safety, pharmacology, or carcinogenic potential.

Parenteral administration of corticosteroids, including clobetasol propionate, to pregnant animals has caused fetal developmental abnormalities such as cleft palate and intrauterine growth retardation. Animal studies suggest potential long-term cardiovascular and metabolic impacts of intrauterine corticosteroid exposure; however, no evidence confirms such effects in humans (see section 4.6).

Fertility studies in rats showed no effects on male fertility at doses of 6.25–50 µg/kg/day subcutaneously. In female rats, high doses led to fetal growth inhibition, thymic atrophy, and embryonic loss.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

- Isopropyl alcohol
- Polysorbate
- Cocamidopropyl betaine
- Propylene glycol
- Macrogol (Polyethylene glycol)
- Purified water

6.2.Incompatibilities

No evidence of incompatibility of PSOBETAZOL with any other drugs or substances has been reported.

6.3.Shelf Life

24 months.

6.4. Special Precautions for Storage

- Store out of the reach and sight of children and in its original packaging.
- Do not use PSOBETAZOL after the expiry date, which is stated on the bottle and carton packaging.
- Store at a temperature below 25°C.
- Once opened, use within 2 months, ensuring it is stored below 25°C.

6.5. Nature and Contents of the Container

PSOBETAZOL is supplied in a 50 mL bottle containing 50 g of product, equipped with a foam pump head and a transparent pump cap.

6.6. Special Precautions for Disposal and Handling

Unused products or waste materials should be disposed of in accordance with the "Regulation on the Control of Medical Waste" and the "Regulation on the Control of Packaging and Packaging Waste."

7. MARKETING AUTHORISATION HOLDER

Drogsan İlaçları San. ve Tic. A.Ş.
Oğuzlar Mahallesi, 1370. Sokak No: 7/3
06520 Balgat-Çankaya/Ankara
Phone: +90 312 287 74 10
Fax: +90 312 287 61 15

8. MARKETING AUTHORISATION NUMBERS

2020/287

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

- First authorisation date: 30.12.2020

10. DATE OF REVISION OF THE SPC

09.03.2021