Clobetasol propionate is a white aerosol foam, supplied as follows:

- **Clobetasol propionate Foam**: 0.05%. Each gram of Clobetasol propionate Foam contains 0.5 mg of clobetasol propionate in a white foam propellant containing water, and stearyl alcohol pressurized with a hydrocarbon (propane/butane) propellant.

**INDICATIONS AND USAGE**

Clobetasol propionate Foam is a corticosteroid indicated for the treatment of moderate to severe plaque psoriasis of non-scalp regions of the body, excluding the face and intertriginous areas in patients 12 years and older.

**CONTRAINDICATIONS**

- **Contraindication**: Clobetasol propionate Foam is contraindicated in patients with known hypersensitivity to any of the ingredients in Clobetasol propionate Foam.

**WARNINGS AND PRECAUTIONS**

- **Allergic Contact Dermatitis**: Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a specific allergic reaction. A trial of therapy with an alternative product may be helpful in these cases.
- **Glucocorticoid-Induced Cushing's Syndrome**: Cushing’s syndrome and hyperglycemia may also occur due to the systemic effects of the topical corticosteroid. If signs or symptoms of Cushing’s syndrome develop, the product should be discontinued and the appropriate diagnostic evaluation initiated.
- **Systemic Adverse Reactions**: Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate the frequency of adverse reactions and that these reactions exist to a greater or lesser degree than reported herein. Local adverse reactions may be reported more frequently with the high potency corticosteroids. The most common adverse reactions associated with Clobetasol propionate Foam are skin thinning, striae, telangiectasia, and striae. Other adverse reactions may include skin atrophy, purpura, allergic contact dermatitis, and increased risk of infections. Clobetasol propionate Foam may suppress the HPA axis. Adrenal insufficiency may occur following the use of topical corticosteroids, especially if used during stressful situations, such as major trauma, surgery, infection, or severe illness. Patients with a history of hypoadrenalinism or hypothyroidism may be particularly sensitive to this effect. The discontinuation of corticosteroids may exacerbate the clinical condition of the underlying disease. Adverse reactions may occur following accidental ingestion or aspiration of topical corticosteroids. Adverse reactions may also occur following ocular exposure to topical corticosteroids.
- **Overdosage**: Should excessive amounts of the topical corticosteroid be accidentally swallowed, a systemic adverse reaction may occur. If this occurs, seek immediate medical attention.

**ADVERSE REACTIONS**

**Clinical trials**: In larger controlled trials with other clobetasol propionate formulations, the most frequently reported local adverse reactions were skin thinning, striae, and telangiectasia (less than 2%).

- **Other clinical trials**: A clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

**OVERDOSAGE**: The most common adverse reaction associated with Clobetasol propionate Foam is skin thinning. Other adverse reactions may include skin atrophy, purpura, allergic contact dermatitis, and increased risk of infections. Clobetasol propionate Foam may suppress the HPA axis. Adrenal insufficiency may occur following the use of topical corticosteroids, especially if used during stressful situations, such as major trauma, surgery, infection, or severe illness. Patients with a history of hypoadrenalinism or hypothyroidism may be particularly sensitive to this effect. The discontinuation of corticosteroids may exacerbate the clinical condition of the underlying disease. Adverse reactions may occur following accidental ingestion or aspiration of topical corticosteroids. Adverse reactions may also occur following ocular exposure to topical corticosteroids.

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**ADVERSE REACTIONS**: Did not report. If no improvement is seen within 2 weeks, contact the physician.

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Important: Clobetasol propionate Foam is for use on the skin only. Do not get Clobetasol propionate Foam near or in your eyes, mouth, or vagina.

How should I apply Clobetasol propionate Foam?

Step 1: Before applying Clobetasol propionate Foam, remove the can from the refrigerator, if you are refrigerating the can. If the foam is cold, run the can under cold water. Be sure to dry them thoroughly before handling the can. You may refrigerate the can, but do not freeze it.

Step 2: Turn the can upside down. Apply the button to squirt a small amount of Clobetasol propionate Foam to the cap of the can, and seal the cap to the can. Apply Clobetasol propionate Foam to the affected areas. (see Figure A)

Step 3: Using your fingertips, gently massage Clobetasol propionate Foam into the affected areas until the foam disappears. (see Figures C and D)

Step 4: If you are treating areas with hair, such as the scalp, move any hair away so that the foam can be applied directly to the affected areas. (see Figure E)

Step 5: Wash your hands after applying Clobetasol propionate Foam. (see Figure F)

How should I store Clobetasol propionate Foam?

Store the Clobetasol propionate Foam at room temperature, Store at 20 - 25°C (68- 77°F) [see USP Controlled Room Temperature]. Contents are flammable. Keep the can away from fire and heat. Do not pierce or burn the can of Clobetasol propionate Foam. Never throw the can into a fire, even if the can is empty.

Keep Clobetasol propionate Foam and all medicines out of the reach of children.

General information about the safe and effective use of Clobetasol propionate Foam.

These are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider about these other uses.

In this leaflet:

- Clobetasol propionate is a medicine that contains clobetasol propionate, the active ingredient in this product.
- This medication is for use on the skin or scalp only.
- Do not give Clobetasol propionate Foam to other people, even if they have the same condition that you have. It may harm them.
- It is not known if Clobetasol propionate Foam is safe and effective in children 12 years of age and younger.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.