

Summary Public Assessment Report
non-generics

CLOBETASOL BELUPO
(clobetasol propionate)

SK/H/0308/001/DC

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CLOBETASOL BELUPO

Clobetasol propionate, shampoo, 500 micrograms/g

This is a summary of the public assessment report (PAR) for CLOBETASOL BELUPO. It explains how CLOBETASOL BELUPO was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use CLOBETASOL BELUPO.

For practical information about using CLOBETASOL BELUPO, patients should read the package leaflet or contact their doctor or pharmacist.

What is CLOBETASOL BELUPO and what is it used for?

CLOBETASOL BELUPO is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but bioequivalence cannot be demonstrated through bioavailability studies.

The company has provided additional own data to demonstrate the safety and efficacy of CLOBETASOL BELUPO regarding this difference from the reference medicine.

The reference medicine for CLOBETASOL BELUPO is Clobex 500 micrograms/g shampoo.

CLOBETASOL BELUPO is used in the topical treatment of moderate scalp psoriasis in adults.

CLOBETASOL BELUPO contains the active substance called clobetasol propionate; it belongs to a group of medicines called topical corticosteroids (or steroids). "Topical" means that it should only be applied to the surface of the skin. Topical steroids reduce the redness, itchiness and inflammation associated with skin conditions.

Scalp psoriasis is caused by the skin cells of your scalp being produced too quickly.

Corticosteroid topical preparations (e.g. shampoo, creams and ointments) come in four different strengths. These are known as mild, moderately potent, potent or very potent.

Clobetasol propionate is classed as a very potent corticosteroid.

How does CLOBETASOL BELUPO work?

Like other topical corticosteroids, CLOBETASOL BELUPO reduce the redness, itchiness and inflammation associated with skin conditions.

How is CLOBETASOL BELUPO used?

The pharmaceutical form of CLOBETASOL BELUPO is shampoo and the route of administration is cutaneous (use on the scalp only).

Adults

The usual daily dose per application is an amount equivalent to around a half tablespoon (around 7.5 ml) sufficient to cover the entire scalp.

Children and adolescents

If this product has been prescribed for children or adolescents between the ages of 2 and 18 years, the instructions given by your doctor must be followed. You must check with the doctor every week before continuing treatment.

Route/method of administration

This product is for use on the scalp only.

Unless your doctor has instructed otherwise, wash your hands and apply CLOBETASOL BELUPO directly to your dry scalp once daily taking care to well cover and massage the affected areas. Avoid using large amounts of CLOBETASOL BELUPO, only use enough to cover your scalp when dry. Wash your hands carefully after application. Leave the product to work for 15 minutes without covering, and then add water, rinse and dry your hair as usual. Your regular shampoo can be used if more shampoo is required to wash your hair. Do not add more of CLOBETASOL BELUPO to your hair.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of CLOBETASOL BELUPO have been shown in studies?

Because CLOBETASOL BELUPO is a hybrid application and is considered to be therapeutically equivalent, to the reference product Clobex, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from CLOBETASOL BELUPO?

The common side effects with CLOBETASOL BELUPO (which may affect up to 1 in 10 people) are skin burning sensation and inflammation of one or more hair follicles.

For the full list of all side effects reported with CLOBETASOL BELUPO, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is CLOBETASOL BELUPO approved?

The State Institute for Drug Control decided that CLOBETASOL BELUPO's benefits are greater than its risks and recommended that it can be approved for use.

Other information about CLOBETASOL BELUPO

The marketing authorisation for CLOBETASOL BELUPO was granted on 23 April 2025.

The full PAR for CLOBETASOL BELUPO can be found on the [website](#). For more information about treatment with CLOBETASOL BELUPO, read the package leaflet ([PL](#)) or contact your doctor or pharmacist.

This summary was last updated in 10-2025.