SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Clobetasol propionate 500 micrograms/g shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of shampoo contains 500 micrograms of clobetasol propionate.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo.
Colourless to slightly yellow, clear to slightly cloudy, viscous shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical treatment of moderate scalp psoriasis in adults.

4.2 Posology and method of administration

Clobetasol propionate belongs to the most potent class of topical corticosteroids (Group IV) and prolonged use may result in serious undesirable effects (see section 4.4). If treatment with a local corticosteroid is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered. Repeated but short courses of clobetasol propionate may be used to control exacerbations (see details below).

Posology

Clobetasol propionate 500 micrograms/g shampoo should be applied directly on dry scalp once daily taking care to well cover and massage the lesions. An amount equivalent to around a half tablespoon (around 7.5 ml) per application is sufficient to cover all the scalp.

The total dosage should not exceed 50 g per week.

Method of administration

For cutaneous use on the scalp only.

After application, clobetasol propionate 500 micrograms/g shampoo should be kept in place without covering for 15 minutes. Hands should be washed carefully after application. After 15 minutes, the product must be thoroughly rinsed with water and/ or hair can be washed by using an additional amount of regular shampoo if needed to facilitate washing. Then, hair can be dried as usual.

The treatment duration should be limited to a maximum of 4 weeks. As soon as clinical results are observed, applications should be spaced out or replaced, if needed, by an alternative treatment. If no improvement is seen within four weeks, reassessment of the diagnosis may be necessary.

Repeated courses of clobetasol propionate 500 micrograms/g shampoo may be used to control exacerbations provided the patient is under regular medical supervision.

Special population

Elderly

The safety and efficacy of clobetasol propionate 500 micrograms/g shampoo in geriatric patients aged 65 years and above have not been established.

Renal impairment

Clobetasol propionate 500 micrograms/g shampoo has not been studied in patients with renal impairment.

Hepatic impairment

Patients with severe liver dysfunction should be treated with special caution and closely monitored for side-effects.

Paediatric population

The experience in the paediatric population is limited. Clobetasol propionate 500 micrograms/g shampoo is not recommended for use in children and adolescents below 18 years of age. It is contraindicated in children under 2 years of age (see sections 4.3 and 4.4).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Clobetasol propionate 500 micrograms/g shampoo must not be applied on skin areas affected by bacterial, viral (varicella, herpes simplex, herpes zoster), fungal or parasitic infections, ulcerous wounds and specific skin diseases (skin tuberculosis, skin diseases caused by lues).

Clobetasol propionate 500 micrograms/g shampoo must not be applied to the eye and eyelids (risk of glaucoma, risk of cataract).

Children under 2 years of age.

4.4 Special warnings and precautions for use

Hypersensitivity to corticosteroids can be observed.

Therefore, clobetasol propionate, is not recommended in patients who are hypersensitive to other corticosteroids.

Long-term continuous therapy with corticosteroids, use of occlusive mobcaps, treatment of large surface areas especially in children can enhance absorption and lead to a higher risk of systemic effects. In such cases, medical supervision should be increased and patients may be evaluated periodically for evidence of HPA axis suppression. Systemic absorption of topical corticosteroids induced by prolonged use especially on large surface areas has caused reversible adrenal suppression with the potential for glucocorticosteroid insufficiency, manifestations of Cushing's syndrome in some patients. Such systemic effects resolve when treatment is stopped. However, abrupt discontinuation can lead to acute adrenal insufficiency, especially in children.

Cases of osteonecrosis serious infections (including necrotizing fasciitis) and systemic immunosuppression (sometimes resulting in reversible Kaposi’s sarcoma lesions) have been reported with long-term use of clobetasol propionate beyond the recommended doses (see section 4.2). In some cases patients used concomitantly other potent oral/topical corticosteroids or immunosuppressors (e.g. methotrexate, mycophenolate mofetil). If treatment with local corticosteroids is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Patient with severe diabetes mellitus should be treated with special caution and closely monitored for side-effects.

Topical corticosteroids should be used with caution as development of tolerance (tachyphylaxis) may occur as well as local toxicity such as skin atrophy, infection and telangiectasia of the skin.

Clobetasol propionate 500 micrograms/g shampoo is only intended for the treatment of scalp psoriasis and should not be used to treat other skin areas. In particular, Clobetasol propionate 500 micrograms/g shampoo is not recommended for use in the face, intertriginous areas (axillae and genitoanal regions) and on other erosive skin surfaces as this could increase the risk of adverse events such as atrophic changes, telangiectasia, corticosteroid-induced dermatitis or secondary infection. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked generalised pustular psoriasis in case of intensive and prolonged topical use.

Clobetasol propionate, is not recommended in patients with acne vulgaris, rosacea or perioral dermatitis.

There may be a risk of post-treatment rebound or relapse upon abrupt discontinuation of treatment with clobetasol propionate. Medical supervision should therefore continue in the post-treatment period.

Topical steroid withdrawal syndrome

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

If clobetasol propionate 500 micrograms/g shampoo does enter the eye, the affected eye should be rinsed with copious amounts of water.

Patients should be instructed to use clobetasol propionate 500 micrograms/g shampoo for the minimum amount of time necessary to achieve the desired results. If signs of local intolerance appear, application should be suspended until they disappear. If signs of hypersensitivity appear, application should be stopped immediately.

In order to avoid interaction with hair colour dying product, such as hair colour changes, clobetasol propionate shampoo should be thoroughly rinsed.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric population

In this age group, growth retardation may also be observed in case of systemic absorption of topical corticosteroids. clobetasol propionate 500 micrograms/g shampoo should not be used in children and adolescents between 2 and 18 years of age.

If clobetasol propionate 500 micrograms/g shampoo is used in children and adolescents below 18 years of age, the treatment should be reviewed weekly.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of topical clobetasol propionate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

Clobetasol propionate 500 micrograms/g shampoo should not be used during pregnancy unless clearly necessary.

Breast-feeding

Systemically administered corticosteroids pass into breast milk. Damage to the infant is not reported to date. Nevertheless, as there are no adequate data on the possible milk transfer of topical clobetasol propionate and its biological or clinical repercussions, clobetasol propionate 500 micrograms/g shampoo should not be prescribed to breastfeeding women unless clearly indicated.

Fertility

No clinical data is available. See section 5.3.

4.7 Effects on ability to drive and use machines

Clobetasol propionate 500 micrograms/g shampoo has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

During clinical development of clobetasol propionate 500 micrograms/g shampoo, in a total of 558 patients receiving clobetasol propionate 500 micrograms/g shampoo, the most commonly reported adverse drug reaction was skin burning sensation. Its incidence was about 2.8%. Most adverse events were rated as mild to moderate and they were not affected by race or gender. Clinical signs of skin irritation were uncommon (0.2%). No serious drug-related adverse events were reported during any of the clinical trials.

Tabulated list of adverse reactions

The adverse reactions are classified by System Organ Class and frequency, using the following convention: 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), not known (cannot be estimated from the available data) and were reported with clobetasol propionate 500 micrograms/g shampoo in clinical studies and post-marketing (see Table 1).

Table 1 – Adverse reactions

System Organ Class	Frequency	Adverse reactions
Endocrine disorders	Uncommon	Adrenal suppression Cushing syndrome
Eye disorders	Uncommon	Eye stinging/burning Eye irritation Ocular tight sensation
	Uncommon	Glaucoma
	Not known	Vision, blurred (see also section 4.4)
Immune System Disorders	Uncommon	Hypersensitivity
Nervous System disorders	Uncommon	Headache
Skin and subcutaneous tissue	Common	Skin burning sensation, Folliculitis

disorders	Uncommon	Pain of skin Skin discomfort Pruritus Acne Skin oedema Telangiectasia Psoriasis (aggravation) Alopecia Dry skin Urticaria Skin atrophy Skin irritation Skin tightness Allergic contact dermatitis, erythema, rash
	Not known	Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

As clobetasol propionate 500 micrograms/g shampoo is to be kept in place for only 15 minutes before rinsing, systemic absorption is seldom observed (see section 5.2) and therefore, the risk of appearance of HPA axis suppression is very low compared to non rinsed potent corticosteroids products. Should HPA axis suppression occur, it is likely to be transient with a rapid return to normal values.

Cataract has been reported when corticosteroids where applied to the eyes or eyelids.

Immunosuppression and opportunistic infections have been reported in case of prolonged use of potent topical corticosteroids in rare instances.

Growth retardation may be observed in children in case of systemic absorption of topical corticosteroids.

Although not observed with clobetasol propionate 500 micrograms/g shampoo, prolonged and/or intensive treatment with potent corticosteroid preparations may cause striae, purpura, and generalised pustular psoriasis.

Rebound effects may occur upon discontinuation of treatment.

When applied to the face, very potent corticosteroids can also induce perioral dermatitis or worsen rosacea.

There are reports of pigmentation changes, pustular eruptions and hypertrichosis with topical corticosteroids.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Acute overdose is very unlikely to occur, however, in the case of chronic overdose or misuse, the features of hypercortisolism may appear and in this situation, treatment should be discontinued gradually. However, because of the risk of acute adrenal suppression, this should be done under medical supervision.

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 has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of topical corticosteroids in general is unclear. However, corticosteroids are thought to act by induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

5.2 Pharmacokinetic properties

In vitro liberation –penetration studies on human skin showed that only a small percentage (0.1 %) of the applied dose of clobetasol propionate shampoo can be found in the epidermis (including the stratum corneum) when applied for 15 minutes and then rinsed. The very low topical absorption of clobetasol propionate from clobetasol propionate shampoo when applied according to the recommended clinical use (15 minutes before rinse off) resulted in negligible systemic exposure in animal studies and in clinical trials. Available clinical data revealed that only 1 of 126 subjects had a quantifiable clobetasol propionate plasma concentration (0.43 ng/ml).

The present pharmacokinetic data indicate that systemic effects following clinical treatment with clobetasol propionate shampoo are highly unlikely due to the low systemic exposure of clobetasol propionate after topical administration.

5.3 Preclinical safety data

Non clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, single, repeated dose toxicity and genotoxicity. The carcinogenicity of clobetasol has not been studied.

In rabbits, clobetasol propionate shampoo was slightly irritating to the skin and eyes, but no delayed-type hypersensitivity was seen on guinea pigs' skin.

In developmental toxicity studies in the rabbit and the mouse, clobetasol propionate was shown to be teratogenic when administered subcutaneously at low doses. In a topical embryotoxicity study of clobetasol in the rat, foetal immaturity and skeletal and visceral malformations were observed at relatively low dosage levels. In addition to malformations, studies in animals exposed to high systemic levels of glucocorticoids during pregnancy have also shown other effects on the offspring, such as intrauterine growth retardation.

The clinical relevance of the effects of clobetasol and other corticosteroids in developmental animal studies is unknown.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Coco alkyl dimethyl betaine
Sodium laurethsulfate
Polyquaternium-10
Sodium citrate
Citric acid monohydrate

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.
Shelf life after first opening: 4 weeks.

6.4 Special precautions for storage

Store in the original container in order to protect from light.

6.5 Nature and contents of container

The product is packaged in high density polyethylene (HDPE) bottles of 125 ml.
The HDPE bottle of 125 ml is fitted with polypropylene cap.
1 g of shampoo corresponds to 1 mL of shampoo.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Vygoris Limited
930 High Road
London, N12 9RT
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 47587/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/02/2026

10 DATE OF REVISION OF THE TEXT

17/02/2026