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## SCHEDULING STATUS

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### 1. NAME OF THE MEDICINE

**GLENCOSOL SHAMPOO** (Viscous liquid)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**GLENCOSOL SHAMPOO:** Each gram of **GLENCOSOL SHAMPOO** contains 0.5 mg of clobetasol propionate.

Excipient of known effect:

One gram of shampoo contains 100 mg of ethanol which is equivalent to 10 % w/w.

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Shampoo (Viscous liquid).

**GLENCOSOL SHAMPOO:** Translucent, colourless to pale yellow viscous liquid.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

**GLENCOSOL SHAMPOO** is indicated for the topical management of moderate to severe plaque-type psoriasis in adults.

#### 4.2 Posology and method of administration

Posology:

**GLENCOSOL SHAMPOO** should be applied directly onto the affected areas twice daily. It should be rubbed gently until completely absorbed. Hands should be washed carefully after application.

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The period of treatment should be limited to 4 weeks and must be adjusted to suit the individual patient (see *section 4.4*).

If further treatment with a topical corticosteroid is required after 4 weeks of treatment with **GLENCOSOL SHAMPOO**, a less potent steroid should be used. Treatment with **GLENCOSOL SHAMPOO** should be stopped if disease control is achieved.

After a period of treatment with **GLENCOSOL SHAMPOO**, the treatment may be repeated to treat exacerbations of psoriasis.

Not more than 50 g of **GLENCOSOL SHAMPOO** should be used per week.

#### *Paediatric population*

The safety and efficacy of **GLENCOSOL** in children and adolescents younger than 18 years of age have not been established.

#### *Method of administration*

For application to the skin.

### **4.3 Contraindications**

- **GLENCOSOL SHAMPOO** is contraindicated in patients with a known hypersensitivity to clobetasol propionate or to any of the excipients in the **GLENCOSOL SHAMPOO** formulation (see *section 6.1*)
- Skin areas affected by bacterial, viral (varicella, herpes simplex, herpes zoster), fungal or parasitic infections and specific skin diseases (skin tuberculosis, skin disease caused by syphilis)
- Acne vulgaris, rosacea or perioral dermatitis (see *section 4.8*)
- Application near the eyes (risk of glaucoma)
- **GLENCOSOL SHAMPOO** should not be applied to ulcerous wounds
- Peri-anal and genital pruritis
- Safety and efficacy have not been established in children younger than 18 years

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#### 4.4 Special warnings and precautions for use

**GLENCOSOL SHAMPOO** should be used with caution for a number of reasons including post-treatment rebound, relapses, development of tolerance (tachyphylaxis) and development of local or systemic toxicity such as atrophy and telangiectasia of the skin or hypothalamic-pituitary-adrenal (HPA) axis suppression.

##### Pustular psoriasis

Treatment of psoriasis with **GLENCOSOL SHAMPOO** (or its withdrawal) may provoke generalised pustular psoriasis in case of intensive and prolonged topical use. Hypersensitivity to **GLENCOSOL SHAMPOO** may occur. This can be suspected in case of resistance to treatment.

##### Hypothalamic-pituitary-adrenal (HPA) axis suppression

**GLENCOSOL SHAMPOO** contains a highly potent topical corticosteroid (clobetasol propionate) that has been shown to suppress the HPA axis at the lowest doses tested. Systemic absorption of topical corticosteroids, as contained in **GLENCOSOL SHAMPOO**, can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which increase systemic absorption include the application of the more potent corticosteroids, use over large surface areas, long-term continuous therapy with **GLENCOSOL SHAMPOO**, and the addition of occlusive dressings or use on occluded areas.

Therefore, patients applying **GLENCOSOL SHAMPOO** to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. If HPA axis suppression is noted, an attempt should be made to withdraw the medicine, to reduce the frequency of application, or to substitute with a less potent steroid.

Recovery of HPA axis function is generally complete upon discontinuation of topical corticosteroids as in PN. Signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic supplementation, see professional information for those medicines.

Medical supervision should be increased, and patients should be evaluated periodically for evidence of HPA axis suppression. Such systemic effects usually resolve when treatment is stopped.

#### Areas of application

Although **GLENCOSOL SHAMPOO** is intended for the topical treatment of moderate to severe scalp psoriasis, it should be noted that certain areas of the body, such as the eyelids, face, groin, axillae and genito-anal regions, are more prone to atrophic changes such as telangiectasia or cortico-induced dermatitis than other areas of the body following treatment with corticosteroids. **GLENCOSOL SHAMPOO** should not be used on the face, groin or axillae. Avoid any contact of the **GLENCOSOL SHAMPOO** with the eyes and lips. If **GLENCOSOL SHAMPOO** does enter the eye, the affected eye should be rinsed with copious amounts of water.

#### Liver dysfunction and diabetes mellitus

Patients with severe liver dysfunction and severe diabetes mellitus should be treated with special caution and closely monitored for adverse effects.

#### Irritation and allergic reactions

If irritation develops, **GLENCOSOL SHAMPOO** should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing.

#### Laboratory tests

The cortrosyn stimulation test may be helpful in evaluating patients for HPA axis suppression

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Paediatric use

The use of **GLENCOSOL SHAMPOO** in patients younger than 18 years old is not recommended due to potential for HPA axis suppression.

Because of a higher ratio of skin surface area to body mass, paediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with **GLENCOSOL SHAMPOO**. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving **GLENCOSOL SHAMPOO**. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Elderly use

Clinical studies of **GLENCOSOL SHAMPOO**, did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently than younger patients. In general, dose selection for an elderly patient should be made with caution, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other medicine therapy.

**4.5 Interaction with other medicines and other forms of interaction**

No interaction studies have been performed.

**4.6 Fertility, pregnancy and lactation**

Pregnancy

Safety in pregnancy has not been established. There are no adequate and well-controlled studies of the teratogenic potential of **GLENCOSOL SHAMPOO** in pregnant women. Studies in laboratory animals have shown reproductive toxicity when administered systemically at relatively low dosage levels. The potential risk for humans is unknown. As a precautionary measure, **GLENCOSOL SHAMPOO** should not be used during pregnancy.

#### Lactation

Systemically administered corticosteroids appear in human milk.

**GLENCOSOL SHAMPOO** should not be prescribed to women breastfeeding their infants.

#### Fertility

Clobetasol propionate decreased fertility when administered intravenously to rats.

### **4.7 Effects on ability to drive and use machines**

As a topical corticosteroid, **GLENCOSOL SHAMPOO** has no or negligible influence on the ability to drive and use machines.

### **4.8 Undesirable effects**

#### a. Summary of the safety profile

The most commonly reported adverse reaction in clinical trials was application site burning, experienced in subjects with **GLENCOSOL SHAMPOO**. Less frequent adverse reactions were application site atrophy, telangiectasia, application site folliculitis, which occurred in subjects treated with **GLENCOSOL SHAMPOO**. All these reactions usually resolved spontaneously.

Other reported adverse reactions in clinical trials included stinging, pruritus, oedema, acne, dry skin, irritant dermatitis and urticaria.

If signs of local intolerance appear, application should be suspended until they disappear. If signs of hypersensitivity appear, application should be stopped immediately.

b. Tabulated summary of adverse reactions

Adverse reactions reported in clinical trials, ordered by System Organ Class (SOC) are tabulated below.

**Table 1: GLENCOSOL SHAMPOO undesirable effects**

MedDRA SOC	Frequency	Adverse events
<b>Infections and infestations</b>	Less frequent	Opportunistic infection
<b>Immune system disorders</b>	Less frequent	Hypersensitivity, generalised rash
<b>Endocrine disorders</b>	Less frequent	Hypothalamic-pituitary adrenal (HPA) axis suppression: Cushingoid features: (e.g. moon face, central obesity), delayed weight gain/ growth retardation in children, osteoporosis, glaucoma, hyperglycaemia/ glucosuria, cataract, hypertension, increased weight/ obesity, decreased endogenous cortisol levels, alopecia, trichorrhexis
<b>Eye disorders</b>	Not known	Blurred vision
<b>Skin and subcutaneous tissue disorders</b>	Frequent	Skin discomfort, pruritus
	Less frequent	Application site dryness, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, milliaria, Skin thinning, skin wrinkling, hypertrichosis, exacerbation of underlying symptoms, dermatitis, pustular psoriasis, erythema, rash, urticaria, acne
<b>General disorders and administration site disorders</b>	Frequent	Application site burning, Telangiectasia, application site atrophy, application site folliculitis, application site pain, application site irritation, headache

c. Selected adverse reactions

*Systemic absorption*

Prolonged use of **GLENCOSOL SHAMPOO** treatment of extensive areas or use of large amounts can result in sufficient systemic absorption to produce the features of hypercortisolism (Cushing's syndrome)

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or HPA axis suppression. Such effects are more likely to occur if occlusive dressings or bandages are used.

#### *Prolonged treatment*

Prolonged and/or intensive treatment with **GLENCOSOL SHAMPOO** may cause local changes, such as local skin atrophy, striae, telangiectasia, erythema, purpura and contact dermatitis, especially with the use of occlusive dressings.

#### *Use in the face*

When applied to the face, **GLENCOSOL SHAMPOO** can induce perioral dermatitis, skin atrophy or worsen rosacea.

There are reports of pigmentation changes, acne, pustular eruptions and hypertrichosis with **GLENCOSOL SHAMPOO**.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/ risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>

#### **4.9 Overdose**

Acute overdose is 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.

Treatment is symptomatic and supportive.

In cases where **GLENCOSOL SHAMPOO** is accidentally swallowed, a healthcare professional should be consulted immediately.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

A 13.4.1 Dermatological preparations – Antipruritics, Corticosteroids with or without anti-infective agents

Clobetasol propionate is a potent corticosteroid which 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 mediator 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

No specific study was performed (*in vivo* or *in vitro*) with clobetasol propionate 500 mg/g. *In vitro* studies in human skin with different formulations of clobetasol propionate demonstrated that clobetasol propionate was recovered mainly in the epidermis (including stratum corneum).

Once absorbed through the skin, topical corticosteroids are handled through metabolic pathways similar to systemically administered corticosteroids, i.e. metabolised primarily by the liver and then excreted by the kidneys.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid monohydrate, coco betaine, ethanol, polyquaternium-10, purified water, sodium citrate dihydrate, sodium laureth sulfate.

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## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf life

24 months

## 6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light. Keep the container tightly closed and in the carton until required for use.

Do not refrigerate or freeze.

## 6.5 Nature and contents of container

**GLENCOSOL SHAMPOO** (Shampoo):

A 118 mL white, opaque, tapered, oval HDPE bottle with flip-top cap.

Each bottle is packed in an outer cardboard carton with a leaflet.

## 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

**Glenmark Pharmaceuticals South Africa (Pty) Ltd**

34 Monte Carlo Crescent,

Block A, First floor,

Kyalami Park, Midrand,

1684

## 8. REGISTRATION NUMBER(S)

55/13.4.1/0073

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**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

12 July 2022

**10. DATE OF REVISION OF TEXT**

1 April 2022