Clean Professional Information

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE SYNALAR SCALP OIL (Topical scalp oil)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of oil contains approximately 0,11 mg of fluocinolone acetonide.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical scalp oil.

Clear, colourless to light straw-coloured liquid filled in a white opaque bottle.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications SYNALAR SCALP OIL is indicated for:

- Psoriasis on the scalp of adult patients.

4.2 Posology and method of administration

Posology:

For the treatment of scalp psoriasis, wet or dampen hair and scalp thoroughly. Apply a thin film of **SYNALAR SCALP OIL** on the scalp, massage well and cover scalp with the supplied shower cap. Leave on overnight or for a minimum of 4 hours before washing off. Wash hair with regular shampoo and rinse thoroughly.

Paediatric population

The safety and efficacy of **SYNALAR SCALP OIL** in children has not yet been established.

4.3 Contraindications

- **SYNALAR SCALP OIL** is contraindicated in patients with a known hypersensitivity to fluocinolone acetonide or to any of the excipients in the **SYNALAR SCALP OIL**

formulation (see *section 6.1*).

- **SYNALAR SCALP OIL** is contraindicated in primary infections of the skin caused by bacteria, fungi or viruses (e.g. herpes, vaccinia or varicella) and in rosacea, acne, peri-oral dermatitis, nappy rash, axillae and anogenital pruritus.
- Pregnancy

4.4 Special warnings and precautions for use

General:

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using Adrenocorticotropic hormone (ACTH) stimulation, A.M. plasma cortisol, and urinary free cortisol tests.

If HPA axis suppression is noted, an attempt should be made to withdraw the medicine, to reduce the frequency of application, or to substitute a less potent corticosteroid. Infrequently, signs and symptoms of glucocorticoid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Children may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than noting a clinical exacerbation, which may occur with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic testing.

If wheal and flare type reactions (which may be limited to pruritus) or other manifestations of hypersensitivity develop, **SYNALAR SCALP OIL** should be discontinued immediately and appropriate therapy instituted.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial medicine should be used. If a favourable response does not occur promptly, use of **SYNALAR SCALP OIL** should be discontinued until the infection has been adequately controlled.

Use in Peanut-Sensitive Individuals:

Medical practitioners should use caution in prescribing **SYNALAR SCALP OIL** for peanut-sensitive individuals. Should signs of hypersensitivity present (wheal and flare reactions, pruritus, or other manifestations), or should disease exacerbations occur, **SYNALAR SCALP OIL** should be discontinued immediately and appropriate therapy instituted.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Pregnancy

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

The use of **SYNALAR SCALP OIL** is contraindicated during pregnancy.

Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk.

Because many medicines are excreted in human milk, caution should be exercised when **SYNALAR SCALP OIL** is administered to breastfeeding women.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

1. Long term continuous treatment with topical corticosteroids should be avoided as far as possible as this may cause atrophic changes in the skin, leading to striae, thinning, loss of elasticity, dilatation of superficial blood vessels, telangiectasia and ecchymosis. These changes are particularly likely to occur on the face and when occlusive dressings are used.

2. Percutaneous absorption of fluocinolone acetonide may lead to both local and systemic toxicity. The extent of percutaneous absorption may be enhanced by the use of occlusive dressings or when the product is applied to parts of the skin which are more permeable. Features of hypercorticism may also be produced. Depression of the hypothalamic-pituitary–adrenal axis with consequent suppression of the adrenal gland may occur. These affects are most likely to be severe in children. Growth may be retarded and a Cushingoid state may be produced. Benign intracranial hypertension has been rarely reported.

3. Irritation at the site of application may occur and hypersensitivity reactions have been reported. Treatment should be discontinued if unfavourable reactions are observed.

4.9 Overdose

Treatment is symptomatic and supportive.

Topically applied **SYNALAR SCALP OIL** can be absorbed in sufficient amounts to produce systemic effects.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.4.1 Corticosteroids with or without anti-infective agents.

Fluocinolone acetonide has anti- inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the 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.

5.2 Pharmacokinetic properties

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusion of topical corticosteroids can enhance penetration. Topical corticosteroids can be absorbed from normal intact skin. Also, inflammation and/or other disease processes in the skin can increase percutaneous absorption.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol, isopropyl myristate, Oleath – 2, peanut oil, light mineral oil and anhydrous citric acid

6.2 Incompatibilities

None

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

Keep the White Opaque PET bottle tightly closed and in the carton until required for use.

Do not refrigerate or freeze.

6.5 Nature and contents of container

White Opaque PET bottle with White Opaque LDPE Nozzle, a 20 mm PET Neck which is capped with a 20 mm RBD screw cap having foam liner and a 20 mm White ribbed OPQ spout cap, containing 118.28 ml of a clear, colourless to light straw-coloured liquid.

Each bottle is packed in an outer cardboard carton with 2 shower caps.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local 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)

55/13.4.1/0064

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 September 2023

10 DATE OF REVISION OF TEXT