TABLE OF CONTENTS – APPROVED PROFESSIONAL INFORMATION JUNE 2026

VR

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SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

MAKLOVATE 500 µg/g SPRAY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MAKLOVATE 500 µg/g SPRAY

One gram of cutaneous spray solution contains 500 micrograms of clobetasol propionate.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Topical spray

MAKLOVATE 500 µg/g SPRAY: Colourless solution, free from any particulates, in a HDPE container.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MAKLOVATE 500 µg/g SPRAY is indicated for the topical treatment of moderate to severe plaque-type psoriasis in adults.

4.2 Posology and method of administration

Posology

For application to the skin:

VR

MAKLOVATE 500 µg/g SPRAY should be sprayed directly onto the affected areas twice daily. It should be rubbed in gently until completely absorbed. Hands should be washed carefully after application. 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 **MAKLOVATE 500 µg/g SPRAY**, a less potent steroid should be used. Treatment with **MAKLOVATE 500 µg/g SPRAY** should be stopped if disease control is achieved. After a period off treatment with **MAKLOVATE 500 µg/g SPRAY**, the treatment may be repeated to treat exacerbations of psoriasis.

Not more than 50 g of cutaneous spray solution should be used per week.

Paediatric population

The safety and efficacy of **MAKLOVATE 500 µg/g SPRAY** in children and adolescents under 18 years of age have not been established.

Method of administration

Topical, Cutaneous

4.3 Contraindications

MAKLOVATE 500 µg/g SPRAY is contraindicated in:

- Hypersensitivity to the active substance or to any of the excipients listed in 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 diseases caused by syphilis)
- Acne vulgaris, rosacea or perioral dermatitis (see Section 4.8).
- **MAKLOVATE 500 µg/g SPRAY** must not be applied to the eyes and eyelids (risk of glaucoma, risk of cataract) or to ulcerous wounds.
- Peri-anal and genital pruritus.
- Pregnancy and Lactation (see section 4.6)

Use in children:

Safety and efficacy has not been established in subjects younger than 18 years of age.

VR

4.4 Special warnings and precautions for use

Clobetasol propionate belongs to the most potent class of topical corticosteroids (Group IV) and prolonged use may result in serious undesirable effects. 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.

Treatment of psoriasis with **MAKLOVATE 500 µg/g SPRAY** (or its withdrawal) may provoke generalised pustular psoriasis in case of intensive and prolonged topical use. Hypersensitivity to **MAKLOVATE 500 µg/g SPRAY** may occur. This can be suspected in case of resistance to treatment. **MAKLOVATE 500 µg/g SPRAY** is not recommended in patients who are hypersensitive to other corticosteroids.

MAKLOVATE 500 µg/g SPRAY is not recommended for use on the eyelids, intertriginous areas (axillae and genito-anal regions) and on other erosive skin surfaces as this could increase the risk of topical adverse events such as atrophic changes, telangiectasia or cortico-induced dermatitis. If **MAKLOVATE 500 µg/g SPRAY** does enter the eye, the affected eye should be rinsed with copious amounts of water.

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

MAKLOVATE 500 µg/g SPRAY 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, infection and telangiectasia of the skin or hypothalamic-pituitary-adrenal axis suppression.

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, mycophenolatemofetil). If treatment with local corticosteroids

VR

is clinically justified beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Treatment of large surface areas, long-term continuous therapy with **MAKLOVATE 500 µg/g SPRAY** or use of occlusive dressings can enhance absorption and lead to a higher risk of systemic effects. Systemic absorption of topical corticosteroids has caused reversible adrenal suppression with the potential for glucocorticosteroid insufficiency, manifestations of Cushing's syndrome, hyperglycaemia, and glycosuria in some patients. Medical supervision should be increased and patients should be evaluated periodically for evidence of hypothalamic-pituitary-adrenal axis suppression. Such systemic effects usually resolve when treatment is stopped. Abrupt discontinuation can lead to acute adrenal insufficiency.

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

Safety and efficacy has not been established in subjects younger than 18 years of age.

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 limited data from the use of clobetasol in pregnant women.

Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown. As a precautionary measure, **MAKLOVATE 500 µg/g SPRAY** should not be used during pregnancy (see section 4.3)

VR

Breast-feeding

Systemically administered corticosteroids pass into breast milk. **MAKLOVATE 500 µg/g SPRAY** should not be prescribed to women breastfeeding their infants (see section 4.3).

Fertility

Clobetasol propionate decreased fertility when administered subcutaneously to rats.

There are no data in humans to evaluate the effect of topical corticosteroids on fertility.

4.7 Effects on ability to drive and use machines

As a topical corticosteroid, **MAKLOVATE 500 µg/g SPRAY** has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The most frequent side-effects experienced was application burning site. Less frequent adverse reactions were application site atrophy, telangiectasia, application site folliculitis. All these reactions usually resolved spontaneously. If signs of local intolerance appear, application should be suspended until they disappear. If signs of hypersensitivity appear, application should be stopped immediately

Table 1: Tabulated summary of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown**
Infections and infestations		Opportunistic infection	

VR

Immune system disorders		Hypersensitivity, generalised rash	
Endocrine disorders		adrenal suppression,-Cushing syndrome	
Skin and subcutaneous tissue disorders	Pruritus, Application site burning , Application site atrophy, Application site folliculitis, Application site pain, Application site irritation Telangiectasia	Application site dryness, Erythema Skin atrophy*, striae*, Skin thinning*, skin wrinkling*, Skin discolouration , hypertrichosis, exacerbation of underlying symptoms, allergic contact dermatitis/dermatitis, pustular psoriasis, erythema, rash, urticaria, acne,	
General Disorders and Administration Site Conditions		Application site irritation/pain	
Eye disorders		Cataract, central serous chorioretinopathy, glaucoma	Vision, blurred

**Skin features secondary to local and/or systemic effects of hypothalamic-pituitary adrenal (HPA) axis suppression.*

VR

Prolonged use of **MAKLOVATE 500 µg/g SPRAY** treatment of extensive areas or use of large amounts can result in sufficient systemic absorption to produce the features of hypercortisolism (Cushing's syndrome) or of Hypothalamus-Pituitary-Adrenal (HPA) axis suppression. Such effects are more likely to occur if occlusive dressings or bandages are used. Prolonged and/or intensive treatment with **MAKLOVATE 500 µg/g SPRAY** may cause local changes, such as local skin atrophy, striae, telangiectasia, erythema, purpura, contact dermatitis especially with the use of occlusive dressings. When applied to the face, **MAKLOVATE 500 µg/g SPRAY** can induce perioral dermatitis, skin atrophy or worsen rosacea. There are reports of pigmentation changes, acne, pustular eruptions and hypertrichosis with Clobetasol propionate, as contained in **MAKLOVATE 500 µg/g SPRAY**.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com.

4.9 Overdose

Symptoms

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 **MAKLOVATE 500 µg/g SPRAY** is accidentally swallowed, a healthcare professional should be consulted immediately.

VR

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class:

A 13.4.1 Dermatological preparation – Antipruritics, Corticosteroids without anti-infective agents

Pharmacotherapeutic group: Corticosteroids, very potent (group IV)

ATC code: D07AD

Mechanism of action

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.

Pharmacodynamic effects

Topical corticosteroids have anti-inflammatory, antipruritic, and vasoconstrictive properties.

5.2 Pharmacokinetic properties

No specific study was performed (*in vivo* or *in vitro*) with clobetasol propionate 500 micrograms/g cutaneous spray, solution.

Absorption

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

Distribution

VR

The use of pharmacodynamic endpoints for assessing the systemic exposure of topical corticosteroids is necessary due to the fact that circulating levels are well below the level of detection.

Metabolism

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. They are metabolised, primarily in the liver.

Elimination

Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol

Isopropyl myristate

Sodium lauryl sulphate

Undecylenic acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacture

6.4 Special precautions for storage

Store at or below 25 °C.

Keep container tightly closed when not in use. Contents are flammable. Keep away from fire, flame or

VR

heat. Do not leave **MAKLOVATE 500 µg/g SPRAY** in direct sunlight.

KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

Round white HDPE bottle with a white polypropylene cap and white plastic pump.

Pack size: 59 ml and 125 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Patients should be advised to wash their hands after applying **MAKLOVATE 500 µg/g SPRAY**. For detailed instructions for use refer to the Patient Information Leaflet in every pack.

Do not use near a naked flame.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

GROUND FLOOR, BLOCK 1,

BASSONIA ESTATE OFFICE PARK (EAST),

1 CUSSONIA DRIVE,

BASSONIA ROCK EXT 12

ALBERTON

GAUTENG

8. REGISTRATION NUMBERS

MAKLOVATE 500 µg/g SPRAY: 58/13.4.1/0178

9. DATE OF FIRST AUTHORISATION

MAKLOVATE 500 µg/g SPRAY: 09 June 2026

VR

10. DATE OF REVISION OF THE TEXT

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