AUSTRALIAN PRODUCT INFORMATION

DESOWEN

Desonide 0.05%

1 NAME OF THE MEDICINE

Desonide

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of DESOWEN lotion, ointment and cream contains 0.5 mg of desonide.

Desonide is a nonfluorinated corticosteroid. Desonide is a white powder or crystal. Practically insoluble in water; sparingly soluble in alcohol and in acetone; soluble in chloroform.

For the full list of excipients, see section 6.1 LIST OF EXCIPIENTS.
DESOWEN Lotion: contains: hydroxybenzoates
DESOWEN Cream: contains sorbates

3 PHARMACEUTICAL FORM

DESOWEN lotion is a white to off-white, soft, smooth lotion.
DESOWEN ointment is a smooth, soft, translucent, grease-like ointment.
DESOWEN cream is a white, shiny, semi-solid emulsion.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Desowen Cream 0.05%, Lotion 0.05% and Ointment 0.05% is indicated for the relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses for adults and children aged 2 years and older.

4.2 DOSE AND METHOD OF ADMINISTRATION

Desowen (desonide) Cream 0.05%, Lotion 0.05% or Ointment 0.05% should be applied as a thin film to the affected areas two to three times daily depending on the severity of the condition. Shake lotion well before using.

Occlusive dressing may be used for the management of psoriasis or recalcitrant conditions. If an infection develops the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

Periods of continuous treatment should not exceed 8 weeks in adults or children.

An increase in the number of daily applications may exacerbate the adverse effects without enhancing the therapeutic effects.

Treatment of large skin areas requires monitoring of the number of tubes used.

4.3 CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

DESOWEN preparations are also contraindicated in most viral infections of the skin (vaccinia, herpes simplex), tuberculosis, acne and rosacea.

Application to ulcerated lesions and to the eyelids is also contraindicated (risk of glaucoma).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Prolonged use of corticosteroids of medium potency on the face is associated with a risk of occurrence of corticosteroid-related dermatitis that is, paradoxically, corticosteroid-responsive, with a rebound after each treatment discontinuation. Gradual withdrawal by tapering is then required.

The product is not recommended in patients with perioral dermatitis.

The product should not be applied on skin areas affected by bacterial and mycobacterial, viral, fungal, parasitic infections or ulcerous wounds.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal axis suppression, manifestations of Cushings syndrome, hyperglycemia and glucosuria in some patients.

Conditions which augment systemic absorption include the application of more potent steroids, use over a large surface area, prolonged use and the addition of occlusive dressings. Therefore patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted an attempt should be made to reduce the frequency of application or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical steroids. Infrequently signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

The duration of continuous treatment should not exceed 8 weeks in either adults or children.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Paediatric use). If signs of skin or subcutaneous atrophy occur discontinue treatment.

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the event of bacterial or fungal superinfection of a corticosteroid-responsive dermatosis, use specific treatment before the corticosteroid treatment. In case dermatological infections develop during treatment with the corticosteroid, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly the corticosteroid should be discontinued until the infection has been adequately controlled.

If signs of local intolerance develop, discontinue the treatment and conduct an etiologic investigation.

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.

FOR EXTERNAL USE ONLY.

Use in the elderly
No data available.

Paediatric use
DESOWEN cream, lotion and ointment should not be administered to children under the age of two years. HPA axis suppression has been assessed in a clinical study in which DESOWEN ointment was administered for 4 weeks. HPA axis suppression has not been assessed during longer periods of administration. Because of a larger skin surface area to body weight ratio, paediatric patients may show a greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients. HPA suppression, Cushing's syndrome and intracranial hypertension have been reported in children using topical corticosteroids. Administration of topical corticosteroids to

children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.
Particular attention must be paid to avoid spontaneous occlusive phenomena, which occur in skin folds or under diapers.

Effects on laboratory tests
No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS
The concomitant use of other corticosteroids in the form of tablets, drops or injections may intensify the side effects.

4.6 FERTILITY, PREGNANCY AND LACTATION
Effects on Fertility
The effect of desonide on fertility has not been investigated in animals or humans.

Use in Pregnancy
Pregnancy category B3.

Corticosteroids may be teratogenic in laboratory animals when administered systemically or topically at relatively low dosage levels and a generic 0.05% desonide cream was reported as teratogenic when applied daily at topical maternal doses of 0.6 and 2g/kg in rats and 2g/kg in rabbits over appropriate gestational periods. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore drugs of this class should be used during pregnancy only if potential benefit justifies the potential risk to the foetus and should not be used extensively, in large amounts, or for prolonged periods.

Use in Lactation:
It is not known whether topical corticosteroids are absorbed sufficiently to be excreted in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless caution should be exercised when topical steroids are administered to a nursing woman. Do not apply the product to the breasts during lactation, due to the risk of product ingestion by the neonate.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)
Prolonged use of corticosteroids of medium potency may induce cutaneous atrophy, telangiectasia (particularly on the face), striae atrophicae (at the roots of the limbs in particular and occurring more readily in adolescents), ecchymotic purpura secondary to atrophy, and cutaneous fragility. On the face, corticosteroids may give rise to peri-oral dermatitis or exacerbate rosacea.

Delayed cicatrization of atonic wounds, decubitus ulcers and leg ulcers may be observed.
Risk of systemic effects (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

The following local adverse reactions are reported infrequently with DESOWEN but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and millaria.

DESOWEN cream, lotion, ointment.
Table 1: Adverse events (> 1%) by type reported in clinical studies.
These are not necessarily drug related.

	Desowen desonide (n = 643)			Hytone hydrocortisone 1% (n = 125)	Aclovate alclomethasone dipropionate 0.05% (n = 60)	Tridesilon desonide (n = 207)
	Ointment (n=118)	Cream (n=447)	Lotion (n=78)			
Body as a whole						
Condition aggravated	-	-		2.4%		
Flu syndrome	3.4%	-				
Pain					1.6%	-
Central Nervous System						
Headache	6.7%					
Insomnia	1.6 %					
Skin & appendage						
Dry skin		-			1.6%	
Exfoliative dermatitis		-			1.6%	-
Pruritis	-	-			1.6%	-
Rash		1.9% #				2.9%
Skin disorder:	1.6% *			2.4% **	1.6%***	
Other events (type not stated)		-			6.6%	

* 1 impetigo & 1 skin infection;
** 1 pediculosis, 1 mite infection, 1 impetigo;
*** smooth skin.
It was not possible to identify the arm of the study in which 'rash' occurred so cream/lotion figures have been pooled**.**

Post-marketing Surveillance

The incidence of adverse drug reactions recorded in global post-marketing surveillance data is less than 1%.

Post Marketing Data

very common	≥ 1/10
common	≥ 1/100 and <1/10
uncommon	≥ 1/1000 and <1/100
rare	≥1/10,000 and <1/1000
very rare	<1/10,000

Body as a whole disorders

Uncommon:	Allergic reaction (including facial oedema and application site reaction)
Rare:	Reaction aggravated (flare up of original condition)

Skin and Appendages disorders

Uncommon:	Rash (irritation including stinging and burning at site of application) Pruritus
Rare:	Skin disorder (not otherwise specified)

Eye disorders
Vision blurred.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see Section 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE).

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity is unclear. There is evidence to suggest a correlation between vasoconstriction and therapeutic efficacy in man. The McKenzie-Stoughton vasoconstrictor assay yields a ranking on a seven-point scale in which the first rank is the most potent. This assay method has been used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. Desonide 0.05% is a group VI corticosteroid when assessed in this way. The DESOWEN preparations are classified as mild topical corticosteroids in the USA where this method of assessment of potency is used. In Europe a four-point measure of potency is used, with one designated the most potent. Desonide 0.05% is ranked 3, a mid-potent topical corticosteroid under this system.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Sufficient corticosteroid may be absorbed to give a systemic effect following topical application. The extent of percutaneous absorption is determined by many factors including the vehicle, the presence of broken skin and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation or other disease processes can increase percutaneous absorption. Occlusive dressings substantially increase percutaneous absorption of topical corticosteroids. Thus occlusive dressings may be a valuable therapeutic adjunct for the treatment of resistant dermatoses.

Distribution

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees.

Metabolism

Corticosteroids are metabolised primarily in the liver.

Excretion

Corticosteroids are excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

There is no information on the genotoxicity of desonide. No mutagenic or clastogenic effects were found following genotoxicity testing of related drugs budesonide and prednisolone.

Carcinogenicity

Desonide has not been investigated in long term carcinogenicity studies in animals. However, budesonide, which has a close structural resemblance to desonide, caused an increased incidence of primary hepatocellular tumours in male rats dosed orally at 25 and 50 μg/kg/day. In a repeat study, budesonide, prednisolone and triamcinolone acetonide all had this effect, indicating a class effect of corticosteroids. A related corticosteroid, flunisolide, caused an increased incidence of pulmonary

adenomas in mice in a 22 month study, and an increased incidence of mammary adenocarcinomas in rats in a 24 month study.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

DESOWEN Lotion
sodium lauryl sulfate
light liquid paraffin
cetyl alcohol
stearyl alcohol
propylene glycol
methyl hydroxybenzoate
propyl hydroxybenzoate
sorbitan monostearate
self emulsifying glyceryl monostearate
edetate sodium
purified water
citric acid
sodium hydroxide

DESOWEN Cream
propylene glycol
polysorbate 60
emulsifying wax
isopropyl palmitate
stearic acid
synthetic beeswax
propyl gallate
citric acid
sodium hydroxide
purified water
sorbic acid
potassium sorbate

DESOWEN Ointment
plastibase 50W (PI 2377)

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Avoid freezing.

6.5 NATURE AND CONTENTS OF CONTAINER

DESOWEN Cream 0.05% and Ointment 0.05% is supplied in tubes (collapsible aluminium tube with white polypropylene cap) containing 25g, 30g, 50g and 60g.

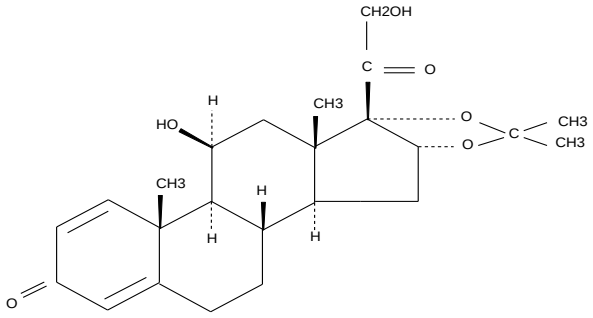
DESOWEN lotion 0.05% is supplied in bottles (HDPE) containing 10mL, 30mL, 60mL and 100mL.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Structural Formula:



Chemical Abstracts Number: 638-94-8
Chemical Name*:* 11β, 16α, 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione-cyclic-16, 17-acetonide.
Molecular Formula: $C_{24}H_{32}O_6$,
Molecular weight : 416.52

7 MEDICINE SCHEDULE (POISONS STANDARD)

PRESCRIPTION MEDICINE (S4)

8 SPONSOR

Galderma Australia Pty Ltd.
13B Narabang Way
Belrose NSW 2085
Australia.
Telephone: 1800 800 765

Distributed in New Zealand by:
Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland

9 DATE OF FIRST APPROVAL

21st December 1998

10 DATE OF REVISION

7th August 2018

Table 2: Summary table of changes

Section changed	Summary of new information
Multiple sections	Reformatting of the PI to comply with the new TGA requirements and addition of safety updates to the sections 4.2, 4.4, 4.6 and 4.8 and minor editorial changes to sections 4.4 and 8 of the PI.
Section 4.4 and Section 4.8	Addition of TGA mandated warning statement (Class effect) related to visual disturbance to Section 4.4 and eye disorder post-marketing adverse effect and new text addition to Section 4.8
Section 4.4	Addition of more restrictive safety statement in the SRR