

Betasone Actavis Cream 0.1%w/w

PRODUCT DESCRIPTION:

White, non-greasy cream.

COMPOSITION:

Betamethasone (as 17-valerate) BP 0.1% w/w

PRESERVATIVES:

Methyl Hydroxybenzoate BP 0.2% w/w

Propyl Hydroxybenzoate BP 0.02% w/w

PHARMACOLOGY:

Betamethasone 17-valerate is a potent topical corticosteroid with mainly glucocorticoid activity with anti-inflammatory, anti-allergic and anti-pruritic actions. It produces a rapid response in those inflammatory dermatoses that are normally responsive to topical corticosteroid therapy, and is also often effective in the less responsive conditions.

PHARMACOKINETIC:

Following topical application to normal skin, Betasone is minimally absorbed. Only small amounts of drug reach the dermis and are then absorbed into the systemic circulation. When applied topically, particularly to large areas, when the skin is broken, or under occlusive dressings, corticosteroids may be absorbed in sufficient amounts to cause systemic effects.

INDICATIONS:

For inflammatory skin disorders.

RECOMMENDED DOSAGE:

Apply sparingly 2-3 times daily, reducing frequency as condition responds.

SIDE EFFECTS:

Prolonged and intensive treatment with Betasone cream may cause local atrophic changes in the skin such as striae, thinning and dilatation of the vessels.

PRECAUTIONS:

Avoid prolonged use in infants and children, and on the face.



AAAN8787 - Betamethasone 0.1% 15g, PIL - Malaysia

GENERAL INFORMATION		TECHNICAL CHECK		COLOURS/PLATES	
Proof Round: 3	Dimensions: 105x171 mm	Date Sent: 01.11.2021		1. Black	●
Origination Date: 01.11.2021	Manuf. site: Actavis Jakarta	Resent Date: 09.11.2021		2.	
Originated by: V.H.	Min pt size*: 10 pt	Approval Date: 12.11.2021		3.	
Revision Date: 18.11.2021	SAP Code:		NON-PRINTING COLOURS	4.	
Revised by: V.H.			1. Profile	5.	
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			3.		



awstudio@tevapharm.com

*Note that smaller packaging dimensions may result in lower point size than your required font size.

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Absorption of Betasone is greater from areas of thin skin, raw surfaces, and intertriginous areas, and is increased by occlusion.

USE IN PREGNANCY:

Although there are no reported adverse effects on pregnancy, there is inadequate evidence of safety in human pregnancy. Therefore, they should not be used extensively on pregnant patients in large amounts or for prolonged periods of time.

CONTRAINDICATION:

Untreated bacterial, fungal or viral skin lesions. Hypersensitivity to any of its components.

DRUG INTERACTION:

No known report of drug interaction for topical application of Betasone.

OVERDOSAGE AND TREATMENT:

Discontinue topical corticosteroid and treat symptomatically.

AVAILABILITY:

15g in aluminium tube.

STORAGE:

Keep below 30°C. Protect from light. Do not freeze.

EXPIRY PERIOD:

Do not use after the expiry date stated on the label.

DATE OF REVISION: November 2021

For further information, please consult your doctor or pharmacist.


Manufactured by:

PT Actavis Indonesia

Jl. Raya Bogor Km. 28, Kelurahan Pekayon, Kecamatan Pasar Rebo
Kota Jakarta Timur, Provinsi DKI Jakarta, Indonesia



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