METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

0239-TDS-ENG-2024

BETAMETASONA VALERATO (EUR. PH.)		
DESCRIPTION DCI: BETAMETHASONE 17-VALERATE	DESCRIPTION DOE: BETAMETASONA 17-VALERATO	
CAS Nº: 2152-44-5	EC Nº: 218-439-3	AEMPS CODE: 491VA
MOL. WEIGHT: 476,60	MOL. FORMULA: C27H37FO6	ARTICLE CODE: 0239

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, freely soluble in acetone and in methylene chloride, soluble in ethanol (96 %)
Melting point	about 192 ºC, with decomposition
Identification A	Complies
Identification C	Complies
Specific optical rotation	+77 / +83
Related substances	
Impurity A	=< 0.7 %
Impurity E	=< 0.3 %
Impurity G	=< 0.3 %
Impurity C	=< 0.15 %
Impurity H	=< 0.15 %
Impurity I	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.5 %
Loss on drying	=< 0.5 %
Assay	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.4

STORAGE

Keep only in the original container in a cool, dry and well-ventilated place.

REMARKS

Betamethasone Valerate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

BETAMETHASONE 17-VALERATE is a corticoid of high potency. It is a salt of betamethasone, which has anti-inflammatory and anti-allergic properties, although this salt facilitates more penetration through the skin. It is used topically in the form of creams, lotions, and ointments to treat different skin disorders, such as contact dermatitis, atopic and seborrheic, eczema, granuloma annulare, intértigo, lichen planus, lupus erythematosus, localized neurodermatitis, anogenital or vulvar pruritus, psoriasis and insect bites. It is also used in the form of touches with elastic collodion in the treatment of vitiligo in small

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areas, not being necessary to accompany it with progressive exposure to sunlight (unlike psoralens).

Dosage
Topical route, 0.01 - 0.25%.

Side effects
In long-term topical therapies it can produce atrophic alterations of the skin, causing collagen destruction, skin striae, hypertrichosis, telangiectasias, and pigmentary disorders. With the application of occlusive bandages, systemic adverse reactions may appear.

Contraindications
Allergy to corticosteroids, infections of viral origin, and tuberculous or lytic processes in the treatment area.

Precautions
In pregnancy and pediatrics its use should be avoided in high doses, extensive areas or prolonged therapies. Do not use in eye treatments or in areas near the eyes.

Incompatibilities
Alkalis, heavy metals, metabisulfites, coal tar, salicylic acid.

Other observations
It is thermolabile.

Compounding examples

Solution for atopic dermatitis and psoriasis
BETAMETASONE 17-VALERATE - **0.2 %**
Salicylic acid - **2 %**
Urea - **10 %**
Hydroalcoholic solution 70% - **75 mL**

Modus operandi: Spray the solids well. Dissolve urea in purified water and salicylic acid and BETAMETHASONE 17-VALERATE in alcohol. Incorporate the second solution on the first.

Collodion for vitiligo
BETAMETASONE 17-VALERATE - **0.2%**
Elastic collodion, c.s.p. - **100 g**

Modus operandi: Weigh BETAMETHASONE 17-VALERATE directly into the final container, add the collodion, close well, and shake until dissolved.