METAPHARMACEUTICAL IND SL
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Technical Data sheet

BETAMETASONA VALERATO (PH.EUR)		
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 B	Complies
Specific optical rotation	+77º / +83º
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 %
Residual solvents	
Methanol	=< 3000 ppm
Acetone	=< 5000 ppm
Methylene chloride	=< 600 ppm
Ethyl acetate	=< 5000 ppm
Particle size	90 % (=< 20 µm)

COMPLIES WITH

European Pharmacopoeia 9.0

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.

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

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

Dosage

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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.