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	Type of Document:	
	<b>TECHNICAL DATA SHEET</b>	
	Review date: <b>13.09.2022</b>	Version: <b>5.0</b>
<b>94315-BETAMETHASONE VALERATE</b>		

## 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

### 1.1 Identification of the substance or preparation

Name: Betamethasone valerate

Bulk code: 94315

### 1.2 Synonyms

Betamethasoni valeras; Betamethasone 17-valerate; Betamethasone 17- $\beta$ -valerate; lubenisolone valerate.

## 2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White or almost white.

Smell: Odourless.

Thermolabile product.

## 3. COMPOSITION/INFORMATION ON COMPONENTS

Formula:  $C_{27}H_{37}FO_6$

CAS No.: 2152-44-5

Molecular weight: 476,6 g/mol

## 4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis report.

**Solubility:** Practically insoluble in water; soluble in 12–16 p. alcohol, 2 p. chloroform, 400 p. ether and 50 p. isopropyl alcohol. Easily soluble in acetone.


**Melting point:** Approximately 192°C with decomposition.

## 5. PROPERTIES/USES

### ACTIVE PHARMACEUTICAL INGREDIENT

Approximately 1.2 mg of betamethasone valerate is equivalent to 1 mg of betamethasone.

This is a betamethasone salt that has the same general effects as betamethasone, however the physico-chemical properties of betamethasone valerate favour its penetration into the skin. It is used topically to treat various skin conditions, such a contact dermatitis, atopic and seborrheic, eczema, ring granuloma, lichen planus, lupus erythematosus, localised neurodermatitis, anogenital pruritus, psoriasis, insect bites. The use of occlusive excipients increases its action.

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It is also used in vitiligo therapy.

## 6. DOSAGE

Topically:

0,01-0,25% in the form of creams, lotions and ointments.

0,2% in collodion for vitiligo treatment.

## 7. REMARKS

### **STORAGE:**

Store at room temperature ( $25\pm 2^{\circ}\text{C}$ ), in a cool, dry place, away from sunlight, in a tightly closed container.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

## 8. BIBLIOGRAPHY

Monografías Farmacéuticas, C.O.F. de Alicante (1998).