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Type of Document:

THECNICAL DATA SHEET

Review date:

08.09.2022

Version:

5.0

## 94153- DEXAMETHASONE BASE

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

#### 1.1. Identification of the substance or preparation.

Name: Dexamethasone base

Bulk code: 94153

#### 1.2. Synonyms.

Dexamethasonum; Hexadecadrol.

### 2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White, almost white.

Smell: Odourless

Flavour: Slightly bitter.

Stable in air.

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula:  $C_{22}H_{29}FO_5$

CAS: 50-02-2

Molecular weight: 392,5 g/mol

### 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in the certificate of analysis.

**Solubility:** Practically insoluble in water; soluble in 42 p. alcohol and 165 p. chloroform. Barely soluble in acetone, dioxane and methanol; very slightly soluble in ether.

**Melting point:** Approximately 255°C with decomposition.

### 5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is a corticoid with high glucocorticoid activity and a slight mineralocorticoid effect. The anti-inflammatory activity of dexamethasone is approximately 27 times greater than that of hydrocortisone and six times more powerful than that of prednisolone.



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It is used to treat all conditions in which treatment with corticoids is recommended, except in conditions of adrenal deficiency. Given its scarce mineralocorticoid activity, it is used to treat cerebral edema and as a suppressor of corticotrophin secretion in congenital adrenal hyperplasia.

Orally, it is used in the differential diagnosis of Cushing's syndrome. It is administered in the same way when treating diverse allergic disorders, like asthmatic bronchitis, although inhalation is preferred, with this method reserved for acute asthma attacks or when the maximum inhalation doses of corticoids and bronchodilators used to maintain it are insufficient; in the case of primary anaphylaxis or angioedema, it is not used as its action is very slow, but it may be given as an adjuvant after an initial emergency application of adrenaline.

It is also used in some blood disorders, such as autoimmune haemolytic anaemia and idiopathic thrombocytopenic purpura; in certain disorders of the connective tissue, like giant cell arteritis, polyarteritis nodosa, polymyalgia rheumatica, polymyositis and systemic lupus erythematosus; in eye inflammations, particularly of the rear socket, and gastrointestinal inflammations like Crohn's disease and ulcerative colitis; in certain renal disorders, such as lupus nephritis and nephrotic syndrome, and hepatic disorders like chronic active autoimmune hepatitis; in some neurological disorders such as infantile spasms and subacute demyelinating polyneuropathies; in certain non-allergic respiratory disorders like pulmonary fibrosis, pulmonary sarcoidosis and some aspiration syndromes; in certain rheumatic and collagen diseases, but rarely in rheumatoid arthritis, and in serious skin disorders, including pemphigus and pemphigoid.

In infections accompanied by severe inflammation, it can be used provided that a suitable anti-infective chemotherapy is administered and that the benefits of the corticosteroid exceed the possible risk of spreading the infection.

Topical use is employed to treat a wide variety of dermatological disorders, such as pruriginous dermatitis, allergic eruptions, solar erythema, psoriasis, seborrheic dermatitis, eczematous pathology and, in general, inflammatory skin processes. It is used to treat alopecia areata.

### **6. DOSAGE.**

Orally, it is administered in starting doses of 500 mcg-9 mg per day, divided into several intakes.

Topically, it is used in the form of solutions and creams at a usual concentration of 0.02-0.1%.

In treating alopecia areata, it is used in solution format up to 2.5%.



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### **7. REMARKS.**

#### **STORAGE:**

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

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

### **8. BIBLIOGRAPHY.**

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).