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Type of Document:

TECHNICAL DATA SHEET

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93692-PREDNISOLONE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Prednisolone

Bulk code: 93692

1.2 Synonyms

Prednisolonum; Cortisal; Δ^1 -Dehydrocortisol; 1,2-Dehydrocortisone; Δ^1 -Dehydrocortisone; Delta F; Delta-Dehydrocortisone; Deltahydrocortisone; Mesterolone; Glucortin; Δ^1 -Hydrocortisone; Hydroretrocortin; Insolone; Intalsolone; Meprisolone; Metacortandralone; Nurisolon; Paracortel; Prenolone.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White or almost white.

Odour: Odourless.

Hygroscopic.

Polymorphic.

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{21}H_{28}O_5$

CAS: 50-24-8 (anhydrous)

Molecular weight: 360,4 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications in analysis report.

Solubility: Soluble in 1,300 p. water, 27 p. absolute alcohol, 30 p. alcohol, 50 p. acetone and 180 p. chloroform; soluble in dioxane and methanol.

Melting point: Approximately 230–235 °C with decomposition.

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT

Prednisolone is a glucocorticoid with anti-inflammatory activity, five times higher than that of cortisone acetate, and antiallergic, used in allergic reactions that are refractory to other therapies, such as allergic rhinitis, drug hypersensitivity, serum sickness, asthma.



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It is also used in congenital adrenal hyperplasia, cancer- and thyroiditis-associated hypercalcaemia; rheumatic conditions, as an adjunct in acute episodes of psoriatic arthritis, bursitis, gouty arthritis, etc.; respiratory disorders such as symptomatic sarcoidosis, berylliosis, aspiration pneumonitis, refractory Loeffler's syndrome to other treatments; nephrotic syndrome, ulcerative colitis, regional enteritis and adrenal hyperfunction diagnostic tests.

6. DOSAGE

Orally:

- In doses of 5–60 mg daily, administered in one or more doses, usually after meals, in the form of capsules and tablets. In cases of inflammatory bowel disease, it can be used in enteric forms.

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. COF Alicante, 1998.

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