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Type of Document:

TECHNICAL DATA SHEET

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3.0

9201 - METHYLPREDNISOLONE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Methylprednisolone

Bulk code: 9201

1.2 Synonyms

Methylprednisolonum; 1-dehydro-6- α -methyl hydrocortisone; 6- α -methyl prednisolone.

2. DESCRIPTION

Appearance: Crystalline powder

Colour: White or almost white

Scent: Odourless

Flavour: Initially insipid but with a lingering bitter aftertaste

Polymorphic

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS No.: 83-43-2

Formula: $C_{22}H_{30}O_5$

Molecular weight: 374,5 g/mol

4. PHYSICO-CHEMICAL DATA

See detailed specifications on the certificate of analysis.


Solubility: Practically insoluble in water, soluble in 100 p. alcohol, 800 p. chloroform and 800 p. ether. Slightly soluble in dehydrated alcohol, acetone and methylene chloride; barely soluble in dioxane and methanol.

Melting point: Approximately 243°C with decomposition.

5. PROPERTIES/USES

ACTIVE PHARMACEUTICAL INGREDIENT

This is a glucocorticoid with an anti-inflammatory and anti-allergy effect; approximately 4 mg of methylprednisolone is equivalent to the anti-inflammatory activity of 5 mg of prednisolone.

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Causes lower sodium and water retention than prednisolone due to its small mineralocorticoid action, for which reason it is not used to treat acute adrenal insufficiency.

It is administered orally in refractory allergic reactions to other treatments, such as allergic rhinitis, hypersensitivity to drugs, serum sickness and asthma.

In addition, it is used in cases of nephrotic syndrome, ulcerative colitis, regional enteritis, hypercalcaemia associated with cancer, thyroiditis and diagnostic proof of overactive kidneys.

It is used as an adjuvant in treating acute episodes of psoriatic arthritis, bursitis, gouty arthritis and other rheumatic disorders.

6. DOSAGE

Orally: Doses of 4-48 mg per day, although higher starting doses are usually required.

7. REMARKS

STORAGE:

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