



GUINAMA Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

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TECHNICAL DATA SHEET

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93916-HYDROCORTISONE ACETATE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation.

Name: Hydrocortisone acetate

Bulk code: 93916

1.2 Synonyms.

Hydrocortisoni acetat; Cortisone acetate; 21-Hydrocortisone acetate; Acetyl hydrocortisone; Acetylated hydrocortisone.

2. DESCRIPTION.

Appearance: Crystalline powder.

Colour: White, almost white.

Smell: Odourless

Flavour: Insipid with lingering bitter aftertaste

Particle size: Micronized

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{23}H_{32}O_6$

CAS: 50-03-3

Molecular weight: 404.5 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in the certificate of analysis.

Solubility: Practically insoluble in water and ether; soluble in 230 p. alcohol, 150-200 p. chloroform, 909 p. acetone, 1,000 p. propylene glycol. Very soluble in dimethylformamide and soluble in dioxane.

Melting point: 220°C, with decomposition.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Approximately 112 mg of hydrocortisone acetate is equivalent to 100 mg hydrocortisone.

This is a glucocorticoid with an anti-inflammatory, anti-allergy and anti-itch effect.

93916-HYDROCORTISONE ACETATE

It is used in inflammatory or allergic skin diseases like contact, atopic and seborrheic dermatitis, inflammatory dermatitis, eczema, lichen planus, lupus erythematosus, localised neurodermatitis, anogenital itching, xerosis, psoriasis and insect bites.

It is also used to treat ulcerative colitis and regional enteritis.

6. DOSAGE.

Topically, it is used at a concentration of 0.1-5% in the form of creams, lotions and ointments. It is also used in the form of retention enemas at 1%.

7. REMARKS.**STORAGE:**

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

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011).