



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

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TECHNICAL DATA SHEET

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93913-HYDROCORTISONE BASE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation

Name: Hydrocortisone base

Bulk code: 93913

1.2 Synonyms

Hydrocortisonum; Compound F; Cortisol; Hydrocortisone; 17-Hydroxycorticosterone;
Anti-inflammatory hormone.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White, almost white.

Smell: Odourless

Polymorphic.

Particle size: Micronized

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{21}H_{30}O_5$

CAS: 50-23-7

Molecular weight: 362.5 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: It is highly soluble in dioxane, soluble in alcohol, acetone and propylene glycol, slightly soluble in chloroform and practically insoluble in water.

Melting point: 214°C with decomposition.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is the main glucocorticoid secreted by the adrenal cortex, which has anti-inflammatory and anti-allergy activity.

It is mainly used orally to as a substitute treatment in acute or chronic adrenocortical insufficiency. It is used in refractory allergic reactions to other treatments, such as allergic rhinitis, hypersensitivity to drugs, serum sickness and asthma.

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It is also used in cases of congenital adrenal hyperplasia, hypercalcaemia associated with cancer and thyroiditis.

It is also used in respiratory disorders, rheumatic disorders and inflammatory or allergic skin diseases, such as contact, atopic and seborrheic dermatitis, inflammatory dermatitis, eczema, granuloma annulare, lichen planus, discoid lupus erythematosus, localised neurodermatitis, anogenital itching, xerosis, psoriasis and insect bites.

It is also used in cases of cold sores and in general inflammatory or ulcerative oral lesions, in preparations with Orabase.

6. DOSAGE.

Orally:

- Normally 10-30 mg per day, administering 20 mg in the morning and 10 mg at night, imitating the body's circadian rhythm.
- In children, doses of 560 mcg/kg of weight per day, in one or several intakes, are recommended
- For other situations (symptomatic sarcoidosis, berylliosis, aspiration pneumonitis and refractory Löffler's syndrome to other treatments, in rheumatic disorders as an adjuvant, in acute episodes of psoriatic arthritis, bursitis, gouty arthritis, etc. nephrotic syndrome, ulcerative colitis, regional enteritis and diagnostic proof of adrenal hyperfunction), doses of 2-8 mg/kg/day, divided into one or several intakes, are recommended.

Topical use:

- At doses of 0.25-2.5% in form of creams, lotions and ointments.

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.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

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