



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

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TECHNICAL DATA SHEET

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## 93946-5-FLUORORACIL

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

#### 1.1 Identification of the substance or preparation

Name: 5-Fluorouracil

Bulk code: 93946

#### 1.2 Synonyms

Fluorouracilum; 2,4-Dioxo-5-fluoropyrimidine; Fluorouracil; 5-FU; 5-Fluoropyrimidine-2,4-dione.

### 2. DESCRIPTION

Appearance: Crystalline powder.

Colour: White or almost white.

Smell: Practically odourless.

Stable in air.

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula:  $C_4H_3FN_2O_2$

CAS: 51-21-8

Molecular weight: 3130.1 g/mol

### 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

**Solubility:** Soluble in 80 p. water and 170 p. alcohol; soluble in dimethyl sulfoxide. Practically insoluble in chloroform, ether and benzene.

**Melting point:** Approximately 282°C with decomposition, turning brown at 230°C.

### 5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is a pyrimidine structural analogue acting as an antimetabolite of uracil, used as an antineoplastic. After its intracellular conversion to active deoxynucleotide, it interferes in the synthesis of DNA by blocking the conversion of deoxyuridylic acid to thymidylic acid via the enzyme thymidylate synthase. It can also interfere in the synthesis of RNA. It also has immunosuppressive properties.

It is used alone or associated in treating inoperable malignant neoplasms, especially in the gastrointestinal tract, chest, liver, genitourinary system and pancreas.

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It may be used topically in cases of solar keratosis, warts, papilloma, psoriasis, leukoplakia, in premalignant tumours and skin conditions, including Bowen's disease and superficial basal cell carcinoma.

It is usually associated with keratolytics to increase its intraepidermal diffusion, as well as with DMSO, although its toxicity also increases.

**6. DOSAGE.**

Orally, it can be used in maintenance doses of 15 mg/kg up to a maximum of 1 g once a week.

Topically:

- It is used in cream or ointment format, or dissolved in propylene glycol of 1-5%, applied twice a day for 10-12 days.
- In Orabase to treat leukoplakia, at a concentration of 4-5%.
- For warts and papilloma, it is used in elastic collodion at a concentration of 5%.

Doses should be reduced in patients with poor nutritional status, deterioration of the bone marrow or liver or kidney function, and following major surgery.

**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". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).