METAPHARMACEUTICAL

TECHNICAL DATA SHEET

000978-TDS-ENG-2025

FLUOROURACILO (EUR. PH.)		
DESCRIPTION DCI: fluorouracil	DESCRIPTION DOE: FLUOROURACILO	
CAS Nº: 51-21-8	EC Nº: 200-085-6	AEMPS CODE: 272A
MOL. WEIGHT: 130,08	MOL. FORMULA: C4H3FN2O2	ARTICLE CODE: 000978

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Sparingly soluble in water, slightly soluble in ethanol (96 per cent)
Identification	Complies
Appearance of solution	Clear and not more intensely coloured than refernce solution Y7 or BY7
pH	4.5 - 5.0
Impurities F and G	
Impurity F	=< 0.25 %
Impurity G	=< 0.2 %
Related substances	
Impurity A	=< 0.1 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Impurity D	=< 0.1 %
Impurity E	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep containers tightly closed, protected from light and moisture.

REMARKS

Fluorouracil is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the

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product before use.

Properties and uses
It is an analog of pyrimidine with antineoplastic action, acting as antimetabolite of uracil and blocking the synthesis of DNA. In addition, it has immunosuppressive properties.
It is used in the treatment of various types of malignant neoplasms.
Topically, it is used in the treatment of solar keratoses, warts, papillomas, psoriasis, oral leukoplakias, and tumors and premalignant conditions of the skin (including Bowen's disease and superficial basal cell carcinoma).
Topically it is selective, not producing alterations in normal skin.
It is usually associated with keratolytics to increase its intraepidermal diffusion, as well as with DMSO to facilitate its degree of division and solubilization and its penetrability in the skin, although its toxicity is also increased.

Dosage
Topical route, 1 - 5% in creams, ointments, or propylene glycol solutions. In cases of warts, at 5% transported in collodion. In cases of leukoplakia, 4 - 5% is transported in an oral adhesive excipient.

Side effects
The toxic effects of FLUOROURACILO can be serious and sometimes fatal.
The main adverse reactions are manifested in the bone marrow and in the gastrointestinal tract, with nausea, vomiting and diarrhea, more frequent at the beginning of therapy. Gastrointestinal toxicity can be enhanced when co-administered with folic acid.
It can produce depression of the bone marrow, with anemia, leukopenia and thrombocytopenia, which usually presents a maximum at 7 - 17 days of treatment. The number of white blood cells reaches the minimum at 7 - 20 days, recovering approximately a month.
Therapy should be discontinued in cases of leukopenia, thrombocytopenia, stomatitis, gastrointestinal ulcer and bleeding, severe diarrhea or hemorrhages.
It also causes central neurotoxicity, eye irritation, cardiac ischemia, alopecia and effects on the skin, which include rashes and hyperpigmentation.
After its topical use, photosensitization reactions and local inflammation have been observed in the sites of application with erythema, exfoliation, and ulceration, which indicates that the preparation is exerting its action.

Contraindications
Contraindicated in pregnancy.

Precautions
It should be administered with caution in debilitated, malnourished individuals with a history of heart disease or kidney or liver failure, as well as in bone marrow depression or bacterial infections.
It is recommended to perform periodic examinations of the blood formula, at the beginning of the treatment every 2 - 3 days, and then every 10 - 14 days.
Before the appearance of hemorrhages or ulcerations therapy should be suspended.
In the treatment of solar keratosis, it is necessary to avoid exposure to the sun or to UV radiation. For very sunny areas, it is advisable to add sunscreens such as p-aminobenzoic acid and a corticoid such as triamcinolone acetonide.
Caution when applied near mucous membranes such as mouth, nose, and eyes. Do not use simultaneously with immunosuppressive chemotherapy or after radiotherapy.
When handling it, use the precautions corresponding to the cytotoxic ones (gloves, mask, exclusive material for this product, etc ...).

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Incompatibilities
Fluoracil-5 preparations are usually adjusted to alkaline pH, showing problems of incompatibility with acid drugs or unstable substances in the presence of alkalis, such as methotrexate, cytarabine, doxorubicin and other anthracyclines, and diazepam.

Other observations
It is photosensitive. Pack the formulas in topaz bottles.

Formulation examples

Ointment for solar keratosis
5-FLUOROURACIL - **5 %**
Vaselina filante c.s.p. - **25 g**

Modus operandi: Finely pulverize the FLUOROURACILO in mortar, moisten with a little liquid petrolatum (5 - 10%), and gradually incorporate the vaseline, homogenizing well with the pistil.

Anti-wart collodion
5-FLUOROURACIL - **5 %**
Salicylic acid - **10 %**
Lactic acid - 1**0 %**
Elastic collodion c.s.p. - **20 g**

Modus operandi: Directly in the container weigh the salicylic acid and add a few drops of acetone to dissolve it. Add the lactic acid and stir. Add the FLUOROURACILO and a little DMSO (approximately 10 g per g of FLUOROURACILO) to finish solubilizing it. Incorporate the collodion, close the container, and shake strongly until it is colorless and without lumps.

Solution for nail psoriasis
5-FLUOROURACILO - **2.5 %**
Propylene glycol - **50 g**

Modus operandi: Weigh the FLUOROURACILO, pulverize it, and gradually add the propylene glycol until homogenization.

Oral adhesive excipient for leucoplasias
5-FLUOROURACIL - **4 %**
Oral adhesive excipient c.s.p. - **20 g**

Modus operandi: Finely pulverize the FLUOROURACILO in mortar, moisten with a little glycerin, and gradually incorporate the oral adhesive excipient, homogenizing well with the pistil.

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