

- Sperm or ovum production disorder
- Secretion of tears
- Blurred vision,
- Inflammation or redness of the lining of the white part of the eye and the underside of the eyelid.
- Eye movement disturbance
- Optic neuritis (a vision disorder characterized by inflammation of the optic nerve)
- Double vision
- Decrease in visual sharpness
- Excessive sensitivity to light and the aversion to sunlight or well-lit places
- Ocular disease characterized by chronic inflammation of the eyelid margins
- Lower eyelid turns outwards
- Blocked tear ducts
- A layer or mass of dead tissue separated from surrounding living tissue, as in a wound, a sore, or an inflammation.
- Liver cell damage

Rare side effects (less than 1 in 1,000 patients):

- Generalized allergic reaction
- Insufficient blood flow in brain, intestine and peripheral organs
- Discoloration of the fingers, toes, and occasionally other areas
- Development of a clot within blood vessels, can occur in arteries or veins
- Swelling (inflammation) of a vein caused by a blood clot
- Severe, whole-body allergic reaction (anaphylaxis)
- Systemic vasodilation (widening of blood vessels) which results in low blood pressure
- Confusion
- Increase of T4 (total thyroxin), increase of T3 (total triiodothyronin)

Very rare side effects (less than 1 in 10,000 patients):

- Cardiac arrest (sudden cessation of heartbeat and cardiac function)
- Sudden cardiac death (unexpected death due to heart problems)
- Symptoms of leucoencephalopathy (diseases affecting the white substance of the brain) including ataxia (loss of the ability to coordinate muscular movement)
- Difficulty in articulating words
- Confusion
- Mental confusion or impaired awareness especially regarding to time, place or identity
- Abnormal muscular weakness or fatigue
- Acute cerebellar syndrome
- Partial or total loss of the ability to communicate verbally or using written words.
- Convulsion or coma in patients receiving high doses of 5-fluorouracil and in patients with dihydropyrimidine dehydrogenase deficiency
- Kidney failure
- Damage of liver cells (cases with fatal outcome)
- Inflammation of the gall bladder
- Slow progressive destruction of the small bile ducts

Not Known (Frequency cannot be estimated from the available data):

- Fever
- Numbness or weakness of the arms and legs
- Hyperammonaemic encephalopathy (brain dysfunction caused by elevated ammonia)
- Inflammation of the skin causing red scaly patches and possibly occurring together with pain in the joints and fever (cutaneous lupus erythematosus [CLE])
- Heart disease that presents with chest pain, shortness of breath, dizziness, fainting, irregular heartbeat (stress cardiomyopathy)
- Air in the intestinal wall
- Serious condition that presents with difficulty breathing, vomiting and abdominal pain with muscle cramps (lactic acidosis)
- Condition characterised by headache, confusion, seizures and changes in vision (posterior reversible encephalopathy syndrome [PRES])
- Serious complication with rapid break down of cancer cells causing high levels of uric acid, potassium and phosphate (tumour lysis syndrome)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUOROURACIL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP.

Store below 25°C. Do not refrigerate or freeze.

Keep container in the outer carton in order to protect from light.

Single use only. Discard any unused portion.

Do not use if the product appears brown or dark yellow in solution.

Do not use this medicine if you notice that the container is damaged or particles/crystals are visible.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fluorouracil contains

- The active substance is fluorouracil.
- The other ingredients are trometamol, sodium hydroxide and water for injections.

What Fluorouracil looks like and contents of the pack

Fluorouracil 50 mg/ml, Solution for injection or Infusion is a clear, colourless to almost colourless solution in a type I clear glass vial with rubber closure.

1 ml of solution contains 50 mg of fluorouracil (as sodium salt formed in situ).

Each 5 ml vial contains 250 mg of fluorouracil.

Each 10 ml vial contains 500 mg of fluorouracil.

Each 20 ml vial contains 1000 mg of fluorouracil.

Each 100 ml vial contains 5000 mg of fluorouracil.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Hikma Farmacêutica (Portugal), S.A.
Estrada do Rio da Mó, 8, 8A e 8B – Fervença
2705-906 Terrugem SNT
Portugal

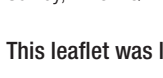
Manufacturer

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Shelf life and storage

Shelf life of unopened vial:

Presentation 250 mg/5 ml – 18 months

Presentation 500 mg/10 ml – 2 years

Presentation 1000 mg/20 ml – 2 years

Presentation 5000 mg/100 ml – 2 years

Shelf Life after dilution

In use: Chemical and physical in-use stability has been demonstrated for 5 days at 20° - 25°C and 2° - 8°C with Water for Injection, Glucose 5% and Sodium Chloride 0.9% solutions at concentrations 0.5 mg/ml, 2.0 mg/ml and 4.0 mg/ml of Fluorouracil.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.