

Fluorouracil Injection

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Fluorouracil Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Fluorouracil Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Fluorouracil Injection is used for

Fluorouracil belongs to a group of medicines known as antineoplastics and is classified as an antimetabolite. Fluorouracil works by preventing the growth of cancer cells and eventually destroying them. It is used for the cancer of the breast, colon, rectum, stomach or the pancreas.

Fluorouracil Injection may be used for the management of other conditions that are not mentioned

above. Your doctor will be able to tell you about the specific condition for which you have been prescribed Fluorouracil Injection.

This medicine is available only with a doctor's prescription.

Before you are given Fluorouracil Injection

When you must not be given it

Do not use Fluorouracil Injection if:

- * you have an allergy to fluorouracil or any of the ingredients listed at the end of this leaflet
- * you have a poor diet
- * you have a low blood count
- * you have a serious infection
- * you are pregnant

If you are not sure whether any of these apply to you, check with your doctor.

Before you are given it

Tell your doctor if:

- 1. you have any allergies to:**
 - * any other medicine
 - * any other substances, such as foods, preservatives or dyes
- 2. you are pregnant or intend to become pregnant**

Fluorouracil Injection is not recommended for use during pregnancy. If it is necessary for you to be given it, your doctor or

pharmacist will discuss the risks and benefits of taking/using it during pregnancy.

3. you are breast-feeding or plan to breast feed

Fluorouracil may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

4. you have received radiotherapy or any other treatment for cancer

5. you have or have had any medical conditions, especially the following:

- * any sort of infection e.g. sinusitis, tooth abscess etc
- * mouth ulcers
- * an ulcer or bleeding in the gut
- * vomiting, diarrhoea
- * any problems of the heart
- * kidney problems or disease
- * liver problems or disease

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and fluorouracil may interfere with each other. These include:

- * other anticancer drugs like methotrexate
- * allopurinol (used to treat gout)
- * metronidazole (used to treat infections)
- * cimetidine (used to reduce acid content in the stomach)

- * folic acid or any vitamin preparation that contains folic or folic acid
- * phenytoin (used to control epilepsy and treat certain cardiac arrhythmias)

Your doctor will advise you about continuing to take other medicines while you are receiving fluorouracil.

How Fluorouracil Injection is given

Fluorouracil is given by injection into a vein. It may also be given by an infusion (slow injection) into a vein or an artery.

Fluorouracil must only be given by a doctor or nurse.

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, sex, blood tests, how well your kidneys and liver are working, and whether or not other medicines are being given at the same time.

If you are given too much (overdose)

This rarely happens as Fluorouracil Injection is administered under the care of a highly trained doctor.

However, if you are given too much fluorouracil, you may experience some of the effects listed under "Side effects" below.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are using Fluorouracil Injection.

Like other medicines, fluorouracil can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions that you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor immediately if you notice any of the following:

- * fever and chills, sore throat, sweats or generally feel unwell
- * chest pains fast or irregular heart beat
- * severe mouth ulcers, mouth soreness, redness of the inside of the mouth
- * difficulty in swallowing
- * severe diarrhoea or abdominal pain
- * a sore rectum or anus, blood in stools or urine
- * severe nausea or vomiting
- * bleeding, unusual bruising, bleeding gums or pinpoint red spots on the skin
- * rash or itching
- * dizziness, muscular weakness, unsteadiness when walking, slurred speech
- * rapid movement of the eye, excess tears, uncomfortable sensitivity to sunlight
- * darkening of the nailbed or any other body area
- * loss of fingernails or toenails
- * a feeling of tiredness, shortness of breath
- * tingling of hands and feet followed by pain, redness and swelling
- * confusion, euphoria, headache

- * memory loss, drowsiness or lack of energy
- * coma and seizures

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately if you notice any of the following and if they worry you:

- * nausea
- * vomiting
- * diarrhoea
- * loss of appetite
- * weakness
- * hair loss
- * changes in skin or nail appearance
- * soreness or ulceration of the mouth

These are more common side effects.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be seen by your doctor.

Storage

Fluorouracil Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays between 15- 25 degrees C.

Product Description

What it looks like

Fluorouracil Injection is a clear, colourless solution in a plastic vial.

Fluorouracil Injection can be identified by an Australian Registration Number, which is found on the packaging: AUST R 11367, AUST R 49308 and AUST R 49309.

Ingredients

Fluorouracil Injection contains Fluorouracil BP 25mg/mL, Sodium Hydroxide BP and Water for Injections BP. It does not contain a preservative.

Manufacturer

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive,
Bentley WA 6102 Australia

Distributed in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia

Sponsor in Australia

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive
Bentley WA 6102 Australia

This Consumer Medicine Information was written in November 2000.

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