Fluorouracil Ebewe
Fluorouracil (Flure-oh-YOOR-a-sill)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluorouracil Ebewe Injection. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Fluorouracil Ebewe Injection against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place. You may need to read it again.

What is Fluorouracil Ebewe used for

Fluorouracil Ebewe belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear of these being called chemotherapy medicines. It is used to treat some types of cancer.

Fluorouracil Ebewe is classified as an 'antimetabolite' type of cytotoxic agent. It works by interfering with the growth of cancer cells which are eventually destroyed. Your doctor may have prescribed Fluorouracil Ebewe for another reason.

Ask your doctor if you have any questions about why Fluorouracil Ebewe has been prescribed for you.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given Fluorouracil Ebewe

When you must not be given it

You should not be given Fluorouracil Ebewe Injection if you have an allergy to Fluorouracil Ebewe or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to Fluorouracil Ebewe Injection may include:
- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin
- dizziness or lightheadedness.

You should not be given Fluorouracil Ebewe Injection if you have any of the following medical conditions:
- problems with blood clotting
- any blood disorder with a reduced number of red blood cells, white blood cells or platelets
- lowered immunity due to diseases including HIV / AIDS or cancer
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)
- you have a poor diet or are debilitated.

Tell your doctor if you have an infection or high temperature.

Like most cytotoxic medicines, fluorouracil is not recommended for use during pregnancy. If there is any need to consider fluorouracil during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are being given fluorouracil or shortly after you have stopped treatment with fluorouracil.

Fluorouracil Ebewe may cause birth defects if either the male or female is receiving it at the time of conception or if it is used during pregnancy. It is recommended that you should use some kind of birth control while you are being treated with Fluorouracil Ebewe and for at least 12 weeks after you stop using it. A barrier method of birth control, such as a condom, should be used while you are being given fluorouracil and for the first week of this 12 week period. Your doctor will discuss this with you.

It is not known whether Fluorouracil Ebewe affects fertility.

Do not breastfeed if you are being treated with this medicine.

It is recommended that you do not breastfeed while being treated with Fluorouracil Ebewe. Fluorouracil Ebewe may pass into breast milk and therefore there is a possibility that the breastfed baby may be affected.

If you are not sure whether you should be given Fluorouracil Ebewe, talk to your doctor.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:
- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:
Fluorouracil Ebewe Injection may be given alone or in combination with other drugs.

Several courses of Fluorouracil Ebewe therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled.

Ask your doctor if you want to know more about the dose of Fluorouracil Ebewe you receive.

How it is given

Fluorouracil Ebewe can be given in three ways:

- as a single injection into a vein
- as a continuous slow injection via a ‘drip’ into a vein
- as a slow injection via a ‘drip’ into an artery.

Fluorouracil Ebewe must only be given by a doctor or nurse.

If you are given too much (overdose)

As Fluorouracil Ebewe Injection is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you experience severe side effects tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of a Fluorouracil Ebewe overdose include the side effects listed below in the ‘Side Effects’ section, but are usually of a more severe nature. Ask your doctor or pharmacist if you have any concerns.

Please contact the Poisons Information Centre in Australia on 131 126 or in New Zealand on 0800 764 766 for advice on overdose management.

While you are being given Fluorouracil Ebewe

Things you must do

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of Fluorouracil Ebewe Injection.

Be sure to keep all your doctor’s appointments so your progress can be checked.

Your doctor may want to do blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of Fluorouracil Ebewe at the appropriate times to get the best effects from your treatments.

Tell any other doctors, dentists and pharmacists who are treating you that you are being given Fluorouracil Ebewe.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Fluorouracil Ebewe.

If you become pregnant while you are being given Fluorouracil Ebewe tell your doctor immediately.

Tell your doctor immediately if you have a fever or infection before, during or after being given Fluorouracil Ebewe Injection.

Fluorouracil Ebewe can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist
may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.

- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Your body breaks down Fluorouracil Ebewe and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

Precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period:

- Flush the toilet twice to dispose of any body fluids and waste
- Wear gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag, seal the bag, and dispose into the garbage. Dispose of the fluids in the toilet
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water
- Place soiled disposable nappies and other pads in a plastic bag, seal the bag and dispose into the garbage
- For sexual intercourse, use a barrier method such as a condom.

**Things to be careful of**

Be careful when driving or operating machinery until you know how Fluorouracil Ebewe Injection affects you.

You may feel tired and weaker while you are receiving treatment. Fluorouracil Ebewe may affect how your kidneys and liver work. Your doctor will arrange regular blood tests to detect any changes.

This medicine may cause dizziness or confusion in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or confusion may be worse.

**Side effects**

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Fluorouracil Ebewe.

Like other medicines that treat cancer, Fluorouracil Ebewe may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

If you are over 70 years of age, you may have an increased chance of getting side effects.

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

**Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:**

- nausea
- vomiting
- diarrhoea
- hair loss
- skin rash
- changes in skin or nail appearance
- euphoria
- headache
- dizziness.

These are some of the more common side effects of Fluorouracil Ebewe.

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

- soreness, redness or ulceration of the mouth, rectum or anus
- unsteady walking
- changes in vision
- jerky eye movements, excess tears, or uncomfortable sensitivity to light
- tingling of the hands and feet followed by pain, redness and swelling
- slurred speech
- disorientation or confusion
- an increased sensitivity of the skin to sunlight (such as redness, itching, swelling, blistering) which may occur more quickly than normal. You should avoid being in the sunlight for too long
- swelling, redness, or pain near the injection site.

These may be serious side effects. Fluorouracil Ebewe may take some time to occur. Therefore, even after you have finished receiving your Fluorouracil Ebewe treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

**After using Fluorouracil Ebewe injection**

**Storage**

Fluorouracil Injection will be stored in the pharmacy or on the ward. It must be protected from light and kept in a cool dry place where the temperature stays below 25°C. It should not be refrigerated or frozen.
Product description

Fluorouracil Ebewe Injection is a clear colourless solution, in a clear glass vial.

Fluorouracil Ebewe comes in the following strengths:

- Fluorouracil Ebewe injection 500 mg of fluorouracil in a 10 mL vial
- Fluorouracil Ebewe injection 1000 mg of fluorouracil in a 20 mL vial

Ingredients

Each vial contains the following ingredients:

Active Ingredient:
• fluorouracil

Other Ingredients:
• Sodium hydroxide
• Water for injections

Fluorouracil Ebewe Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Vial stopper is not made with natural rubber latex.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Australia
Tel: 1800 726 369

Australian Registration Numbers

500 mg in 10 mL   AUST R 98544
1000 mg in 20 mL   AUST R 98545

Fluorouracil Ebewe is distributed in New Zealand by:

Novartis New Zealand Ltd
PO Box 99102
Newmarket
Auckland 1149
Tel: 0800 354 335

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