

# Fluorouracil Ebewe

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

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## Consumer Medicine Information

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### What is in this leaflet

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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.

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### What is Fluorouracil Ebewe used for

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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.

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### Before you are given Fluorouracil Ebewe

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*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:

- 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).

**Tell your doctor if you have an infection or high temperature.** Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

**You should not be given Fluorouracil Ebewe if you are pregnant or plan to become pregnant.** Like most medicines used to treat cancer, Fluorouracil Ebewe is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

**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.** 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.

Your doctor will discuss this with you.

It is not known whether Fluorouracil Ebewe affects fertility.

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:**

- heart disease
- kidney disease
- liver disease
- problems with stomach or intestinal ulcers
- haemorrhoids/piles or other bleeding in or from the bowels
- problems with blood clotting
- if you have had previous radiation treatment or other cancer treatment
- if you have any known enzyme deficiencies.

**Tell your doctor if you are breast-feeding or plan to breast-feed.** It is recommended that you do not breast-feed while being treated with Fluorouracil Ebewe. Fluorouracil Ebewe may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

**If you have not told your doctor about any of the above, tell them before you are given Fluorouracil Ebewe.**

### ***Taking other medicines***

**Tell your doctor or pharmacist 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 Ebewe may interfere with each other. These include:

- some medicines used to treat gout (eg allopurinol)
- some medicines used to treat some types of cancer (eg methotrexate)
- some medicines used to treat some types of infections (metronidazole)
- folinic acid (used as an antidote to some cancer therapy)
- cimetidine (used to treat stomach ulcers).

These medicines may be affected by Fluorouracil Ebewe, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you. Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given Fluorouracil Ebewe.

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### **How Fluorouracil Ebewe is given**

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#### *How much is given*

Your doctor will decide what dose of Fluorouracil Ebewe you will receive. This depends on your medical condition and

other factors, such as your weight and height. 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.

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## While you are being given Fluorouracil Ebewe

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### *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.

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.

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

### *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 being treated with Fluorouracil Ebewe.

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## Side effects

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**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.

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
- 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
- swelling, redness, or pain near the injection site.

These may be serious side effects

**Tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:**

- chest pain

- irregular and/or rapid heart beat
- signs of an infection (eg fever, chills, sore throat, cough)
- unusual bleeding or bruising (such as bloody or black stools, blood in urine)
- severe abdominal pain
- severe mouth ulceration
- difficulty swallowing
- any signs of an allergic reaction such as those listed at the start of this leaflet.

**These may be serious side effects. You may need medical attention.**

Treatment with Fluorouracil Ebewe may cause changes in your blood cells which may be serious. Fluorouracil Ebewe may also affect how your kidneys and liver work. Your doctor will arrange regular blood tests to detect any changes.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

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

**The benefits and side effects of 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.**

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## **After using Fluorouracil Ebewe injection**

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## *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.

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## **Product description**

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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 1000mg 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.

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## **Manufacturer**

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Fluorouracil Ebewe is made by EBEWE Pharma GmbH Nfg KG A-4866, Unterach AUSTRIA

## **Sponsor**

Fluorouracil Ebewe is distributed in Australia by:

InterPharma Pty Ltd  
Suite 3, 14 Sydney Road  
Manly  
NSW 2095

### Australian Registration Numbers

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

This leaflet was prepared in March 2006.