

FLUOROURACIL ACCORD

Fluorouracil Injection Solution 250 mg/5 mL, 500 mg/10 mL, 1 g/20 mL, 2.5 g/50 mL and 5 g/100 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fluorouracil Accord.

It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

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

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

Keep this leaflet with the medicine. You may need to read it again.

What Fluorouracil Accord is used for

Fluorouracil Accord 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 Accord 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, however, may prescribe Fluorouracil Accord for another purpose.

Ask your doctor, nurse or pharmacist if you have any questions about why Fluorouracil Accord has been prescribed for you.

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

Fluorouracil Accord is not addictive.

Before you are given it

When you must not be given it

Do not receive Fluorouracil Accord if you have an allergy to Fluorouracil or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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 light-headedness.

Do not receive Fluorouracil Accord if you have, or have had, 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, ciclosporin or other medicines used to treat cancer (including radiation therapy).
- you have a poor diet or are debilitated.

Fluorouracil must not be taken within 4 weeks of treatment with brivudine, sorivudine or their chemically related analogues.

Do not receive it if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, Fluorouracil Accord is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Fluorouracil Accord 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 Accord and for at least 12 weeks after you stop using it.

Your doctor will discuss this with you.

It is not known whether Fluorouracil Accord affects fertility.

Tell your doctor if you are breastfeeding or planning to breastfeed.

It is recommended that you do not breast-feed while being treated with Fluorouracil Accord. Fluorouracil Accord may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Do not receive it after the expiry date (EXP) printed on the carton.

If you receive it after the expiry date has passed, it may not work as well.

Do not receive it if the packaging is damaged or shows signs of tampering.

If you are not sure whether you should be receiving Fluorouracil Accord, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if you have allergies to:

- any of the ingredients listed at the end of this leaflet
- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Fluorouracil Accord is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of being given it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Fluorouracil Accord may pass into breast milk. Your doctor will discuss the risks and benefits of being given it if you are breast-feeding or planning to breast-feed.

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 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.

Tell your doctor if you plan to have surgery.

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

Taking other medicines or treatments

Tell your doctor, nurse 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 Accord may interfere with each other. These include:

- some medicines used to treat gout (e.g. allopurinol)
- some medicines used to treat some types of cancer (e.g. 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)
- brivudine, sorivudine or their chemically related analogues.

These medicines and treatments may be affected by Fluorouracil Accord, or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you.

Your doctor, nurse or pharmacist has more information on medicines to be careful with or to avoid while being given Fluorouracil Accord.

How it is given

Fluorouracil Accord should only be administered by trained professionals, with appropriate handling, in a hospital or clinic environment.

Fluorouracil Accord is for single use in one patient only. Any unused residue should be discarded.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and height.

Fluorouracil Accord Injection may be given alone or in combination with other drugs. Several courses of Fluorouracil Accord 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 Accord you receive.

How it is given

Fluorouracil Accord may be given in three (3) 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.

If you receive too much (Overdose)

As Fluorouracil Accord is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Fluorouracil Accord, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

Symptoms of a Fluorouracil Accord overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Please contact the Poisons Information Centre in Australia on 13 11 26 or in New Zealand on 0800 764 766 for advice on overdose management.

While you are being given it

Things you must do

Be sure to keep all your doctor's appointments.

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

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

Tell all the doctors, dentists, and pharmacists who are treating you that you are being given Fluorouracil Accord.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Fluorouracil Accord.

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

Tell your doctor immediately if you have a fever or infection before, during or after being given Fluorouracil Accord. Fluorouracil Accord 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 or nurse immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, pain in the lower back or side or you 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 Accord 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 Accord Injection affects you.

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

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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 the more common side effects of Fluorouracil Accord.

Tell your doctor, nurse or pharmacist 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.

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

- chest pain
- loss of fingernails or toenails
- irregular and/or rapid heart beat
- signs of an infection (e.g. 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 urgent medical attention or hospitalisation.

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

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor to answer any questions you may have.

The benefits and side effects of Fluorouracil Accord may take some time to occur. Therefore, even after you have finished your Fluorouracil Accord treatment you should tell your doctor or nurse immediately if you notice any of the side effects listed in this section.

After being given it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or pharmacist.

Storage

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

Product Description

What it looks like

Fluorouracil Accord single-dose vials contain a clear colourless solution. It is available in 5 presentations; 250 mg/5 mL, 500 mg/10 mL, 1 g/20 mL, 2.5 g/50 mL and 5 g/100 mL in single packs.

Ingredients

Active Ingredient:

Fluorouracil

Inactive ingredients:

Water for Injection

Sodium hydroxide

Hydrochloric acid

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

Name and Address of the Sponsor

Accord Healthcare Pty Ltd.
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

Australian Registration Number

250 mg/5 mL: AUST R 285799

500 mg/10 mL: AUST R 285801

1 g/20 mL: AUST R 285800

2.5 g/50 mL: AUST R 285803

5 g/100 mL: AUST R 285802

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This leaflet was prepared on 07 July 2020.