

# FLUOROURACIL ACCORD

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I being given Fluorouracil Accord?

Fluorouracil Accord contains the active ingredient Fluorouracil. Fluorouracil Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents. 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.

For more information, see Section [1. Why am I using Fluorouracil Accord?](#) in the full CMI.

### 2. What should I know before I am given Fluorouracil Accord?

Do not use if you have ever had an allergic reaction to any medicine containing Fluorouracil or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given Fluorouracil Accord?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Fluorouracil Accord and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given Fluorouracil Accord?

Fluorouracil Accord will be given to you by a doctor or a nurse.

More instructions can be found in Section [4. How will I be given Fluorouracil Accord?](#) in the full CMI.

### 5. What should I know while being given Fluorouracil Accord?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor immediately if you have a fever or infection before, during or after being given Fluorouracil Accord.</li><li>• If you become pregnant during or soon after being given Fluorouracil Accord, tell your doctor.</li><li>• Tell the surgeon or anaesthetist that you are being given Fluorouracil Accord if you are going to have surgery.</li></ul>
<b>Driving or using machines</b>	Be careful driving or operating machinery until you know how Fluorouracil Accord affects you.  Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or confusion may be worse.

For more information, see Section [5. What should I know while being given Fluorouracil Accord?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the serious side effects are:

Any signs of an allergic reaction (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); soreness, redness or ulceration of the mouth, rectum or anus; unsteady walking, muscle weakness or muscle cramps; 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; memory loss, 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; fever; pain, stiffness or swelling in joints; swelling, redness, or pain near the injection site; chest pain; loss of fingernails or toenails; irregular and/or rapid heart beat; loss of consciousness; signs of an infection (e.g. fever, chills, sore throat, cough, pain with urination, swollen or red skin); unusual bleeding or bruising (such as bloody or black stools, blood in urine); yellowing of the skin or eyes; severe diarrhoea; severe abdominal pain; severe mouth ulceration; difficulty swallowing; seizures, coma.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FLUOROURACIL ACCORD

**Active ingredient(s):** *Fluorouracil*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fluorouracil Accord. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fluorouracil Accord.**

### Where to find information in this leaflet:

- [1. Why am I being given Fluorouracil Accord?](#)
- [2. What should I know before I am given Fluorouracil Accord?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Fluorouracil Accord?](#)
- [5. What should I know while being given Fluorouracil Accord?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given Fluorouracil Accord?

**Fluorouracil Accord contains the active ingredient Fluorouracil.** 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.

## 2. What should I know before I am given Fluorouracil Accord?

### Warnings

#### You must not be given Fluorouracil Accord if:

- you have an allergy to Fluorouracil or to any of the other ingredients listed at the end of this leaflet.
- 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, complete dihydropyrimidine dehydrogenase (DPD) deficiency.

#### Tell your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives

- 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)
- plan to have surgery
- are within four weeks of treatment with brivudine, sorivudine or their chemically related analogues

#### Tell your doctor if you have or have had:

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Tell your doctor if you:

- are pregnant, or intend to become pregnant
- are breastfeeding or plan to breastfeed.

Like most medicines, Fluorouracil Accord is not recommended for use during pregnancy. Your doctor will discuss with you the risks and benefits of having Fluorouracil Accord during pregnancy.

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 3 months (for male patients) and 6 months (for female patients) after you stop using it.

It is not known whether Fluorouracil Accord affects fertility.

You should not breast-feed your child during your treatment with Fluorouracil Accord. Fluorouracil Accord may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

## 3. What if I am taking other medicines?

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

**Some medicines and Fluorouracil Accord may interfere with each other.**

#### Tell your doctor if you are taking:

- medicines used to treat gout (e.g. allopurinol)

- medicines used to treat some types of cancer (e.g. methotrexate)
- medicines used to treat some types of infections (e.g. metronidazole)
- phenytoin (used to treat epilepsy)
- warfarin (used to prevent blood clots)
- folinic acid (used as an antidote to some cancer therapy)
- cimetidine (used to treat stomach ulcers)
- brivudine, sorivudine or their chemically related analogues.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fluorouracil Accord.**

#### 4. How will I be given Fluorouracil Accord?

Fluorouracil Accord will be given to you by a doctor or a nurse. It 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.

#### How much will be given

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

#### When will Fluorouracil Accord be given

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.

#### If you receive too much Fluorouracil Accord

Since Fluorouracil Accord is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Fluorouracil Accord.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, nurse or pharmacist.

#### 5. What should I know while being given Fluorouracil Accord?

##### Things you should 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 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.

Fluorouracil and its 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.

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

**If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Fluorouracil Accord.**

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are being given Fluorouracil Accord.**

##### Driving or using machines

**Be careful driving or operating machinery until you know how Fluorouracil Accord 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.

## Looking after your medicine

The hospital will store Fluorouracil Accord under the correct conditions.

## Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Fluorouracil Accord that may be left over.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Common side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>nausea</li> <li>vomiting</li> <li>diarrhoea</li> <li>loss of appetite</li> <li>hair loss</li> <li>skin rash</li> <li>changes in skin or nail appearance</li> <li>euphoria</li> <li>tiredness</li> <li>headache</li> <li>dizziness</li> <li>fatigue</li> <li>irritability</li> <li>restlessness</li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>any signs of an allergic reaction (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)</li> <li>soreness, redness or ulceration of the mouth, rectum or anus</li> <li>unsteady walking, muscle weakness or muscle cramps</li> <li>changes in vision, jerky eye movements, excess tears or uncomfortable sensitivity to light</li> <li>tingling of the hands and feet followed by pain, redness and swelling</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>slurred speech</li> <li>memory loss, disorientation or confusion</li> <li>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</li> <li>fever</li> <li>pain, stiffness or swelling in joints</li> <li>swelling, redness, or pain near the injection site</li> <li>chest pain</li> <li>loss of fingernails or toenails</li> <li>irregular and/or rapid heart beat</li> <li>loss of consciousness</li> <li>signs of an infection (e.g. fever, chills, sore throat, cough, pain with urination, swollen or red skin)</li> <li>unusual bleeding or bruising (such as bloody or black stools, blood in urine)</li> <li>yellowing of the skin or eyes</li> <li>severe diarrhoea</li> <li>severe abdominal pain</li> <li>severe mouth ulceration</li> <li>difficulty swallowing</li> <li>seizures, coma</li> </ul>	

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 or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription. Fluorouracil Accord is not addictive.

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

## What Fluorouracil Accord contains

<b>Active ingredient (main ingredient)</b>	fluorouracil
<b>Other ingredients (inactive ingredients)</b>	sodium hydroxide hydrochloric acid water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Fluorouracil Accord looks like

Fluorouracil Accord is a clear colourless solution supplied in single packs. (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)

## Who distributes Fluorouracil Accord

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

This leaflet was prepared in September 2023.