

DBL™ Fluorouracil Injection BP

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

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Fluorouracil Injection BP

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 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.

You may need to read it again.

What DBL™ Fluorouracil Injection BP is used for

This medicine is used to treat some types of cancer.

This medicine belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

It works by killing cancer cells and stopping cancer cells from growing and multiplying. It may be used alone or in combination with other medicines to treat cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed fluorouracil for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given DBL™ Fluorouracil Injection BP

When you must not be given it

You should not be given DBL™ Fluorouracil Injection BP if you have an allergy to fluorouracil.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

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.

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

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 may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are using fluorouracil and for at least 12 weeks after you stop treatment. 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.

Do not breast-feed if you are being treated with this medicine.

It is not known whether fluorouracil passes into breast milk, and there is a possibility that your baby may be affected.

You must not be given this medicine 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

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any medical conditions, especially the following:

- heart disease
- kidney disease
- liver disease
- any known enzyme deficiencies.

Tell your doctor if you have had previous radiation treatment or other cancer treatment.

If you have not told your doctor about any of the above, tell him/her before you are given fluorouracil.

Taking other medicines

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

Some medicines and fluorouracil may interfere with each other.

These include:

- allopurinol (used to treat gout)
- metronidazole (used to treat some types of infections)
- cimetidine (used to treat stomach ulcers)
- leucovorin (folinic acid) (used as an antidote to some cancer therapy)
- levamisole (used to treat a type of colon cancer)
- methotrexate and other medicines used to treat cancer).
- phenytoin (used to treat epilepsy)

These medicines may be affected by fluorouracil, 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 and pharmacist may have more information on medicines to be careful with or

avoid while being given this medicine.

How DBL™ Fluorouracil Injection BP is given

How much is given

Your doctor will decide what dose you will receive. This depends on your medical condition and other factors, such as your weight and height, blood cell numbers, and renal and liver function.

DBL™ Fluorouracil Injection BP may be given alone or in combination with other drugs to treat cancer.

Several courses of fluorouracil 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 you receive.

How it is given

Fluorouracil can be given in three ways:

- as an 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 must only be given by a doctor or nurse.

If you are given too much (overdose)

As DBL™ Fluorouracil Injection BP is given to you 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.

Symptoms of an overdose may 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 DBL™ Fluorouracil Injection BP

Things you must do

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

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

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

Keep all of 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 at the appropriate times to get the best effects from your treatments.

This medicine 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 and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste
- Wearing 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 and dispose of fluids in the toilet
- Washing 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
- Placing soiled disposable nappies and other pads in a

plastic bag, seal and dispose into the garbage

- For sexual intercourse, use a barrier method such as a condom.

Things to be careful of:

Be careful driving or operating machinery until you know how fluorouracil 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

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with fluorouracil.

Like other medicines that treat cancer, fluorouracil 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.

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.

The above list includes side effects that are usually mild or short lived.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- sore mouth, mouth ulcers
- 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.

The above list includes serious side effects, which may require medical attention.

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 shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention.

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 people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

After using DBL™ Fluorouracil Injection BP

Storage

DBL™ Fluorouracil Injection BP 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 between 8- 25°C. It should not be refrigerated or frozen.

Product description

What it looks like

DBL™ Fluorouracil Injection BP is a clear colourless to slightly yellow solution, in a clear glass vial.

Fluorouracil comes in the following strengths*:

- DBL™ Fluorouracil Injection BP 250mg/10mL, in packs of 5 AUST R 16335
- DBL™ Fluorouracil Injection BP 500mg/20mL, available in packs of 10 AUST R 47262
- DBL™ Fluorouracil Injection BP 250mg/5mL, in packs of 5 AUST R16331

- DBL™ Fluorouracil Injection BP 2.5g/100mL, available in packs of 1 AUST R 47263
 - DBL™ Fluorouracil Injection BP 500mg/10mL, available in packs of 5 AUST R 47260
 - DBL™ Fluorouracil Injection BP 1g/20mL, available in packs of 5 AUST R 64403
 - DBL™ Fluorouracil Injection BP 2.5g/50mL, available in packs of 1 AUST R 75832
- * Not all presentations are marketed

Ingredients

DBL™ Fluorouracil Injection BP contains fluorouracil as the active ingredient. It also contains:

- Sodium hydroxide
- Water for injections

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

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
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New Zealand

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