

DBL™ Fluorouracil Injection BP

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, nurse or pharmacist.

1. Why am I being treated DBL Fluorouracil Injection BP?

DBL Fluorouracil Injection BP contains the active ingredient fluorouracil. DBL Fluorouracil Injection BP is used to treat some types of cancer.

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

2. What should I know before treatment with DBL Fluorouracil Injection BP?

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

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

For more information, see Section [2. What should I know before I use DBL Fluorouracil Injection BP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Fluorouracil Injection BP 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 is DBL Fluorouracil Injection BP given?

Your doctor will decide what dose you will receive. This depends on your medical condition and other factors. Fluorouracil must only be given by a doctor or nurse. More instructions can be found in Section [4. How do I use DBL Fluorouracil Injection BP?](#) in the full CMI.

5. What should I know while being treated with DBL Fluorouracil Injection BP?

There are many important things to consider while you are taking this medicine. The most common and serious considerations are summarised below (see the full CMI for more details).

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist

	<p>you visit that you are using DBL Fluorouracil Injection BP.</p> <ul style="list-style-type: none"> ● Tell your doctor immediately if you become pregnant; keep all your doctor's appointments so your progress can be checked. ● Take precautions to reduce your risk of infection or bleeding. ● Take precautions to protect other people while being treated with this medicine and for one week after.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how fluorouracil affects you. ● This medicine may cause tiredness, dizziness or confusion in some people.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Alcohol may make any dizziness or confusion worse.

Looking after your medicine	<ul style="list-style-type: none">• This medicine is stored at the hospital.
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For more information, see Section [5. What should I know while using DBL Fluorouracil Injection BP?](#) in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include nausea; vomiting; diarrhoea; yellowing of the skin or eyes, loss of appetite; hair or nail loss; changes in skin or nails; euphoria; tiredness; headache; dizziness; fatigue; irritability; restlessness; sore mouth; mouth ulcers; sore rectum or anus; unsteady walking; muscle weakness or muscle cramp; changes in vision; jerky eye movements; excess tears; sensitivity of eyes to light or skin to sunlight; fever; pain, stiffness or swelling in joints; tingling and pain of the hands and feet; redness and swelling; slurred speech; memory loss; confusion; swelling, redness or pain near the injection site; chest pain; irregular and/or rapid heart-beat; loss of consciousness; infection; unusual bleeding or bruising; severe abdominal pain; difficulty swallowing; fits; coma; allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling; rash, itching or hives on the skin). For more information, see Section [6. Are there any side effects?](#) in the full CMI

DBL™ Fluorouracil Injection BP

Active ingredient: *fluorouracil*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I using DBL Fluorouracil Injection BP?](#)
- [2. What should I know before treatment with DBL Fluorouracil Injection BP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Fluorouracil Injection BP given?](#)
- [5. What should I know while being treated with DBL Fluorouracil Injection BP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Fluorouracil Injection BP?

DBL Fluorouracil Injection BP contains the active ingredient fluorouracil. DBL Fluorouracil Injection BP belongs to a group of medicines called antineoplastic or

cytotoxic medicine. 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.

This medicine is used to treat some types of cancer including breast, colon, rectum, stomach, liver, pancreatic, uterine (cervical particularly), ovarian and bladder cancer.

2. What should I know before treatment with DBL Fluorouracil Injection BP?

Warnings

Do not use DBL Fluorouracil Injection BP if you:

1. are allergic to fluorouracil, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
2. have an infection or high temperature.
3. have any blood disorder with a reduced number of red blood cells, white blood cells or platelets.
4. have problems with blood clotting.
5. have a lowered immunity due to diseases including HIV / AIDS or cancer.
6. have a lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other

medicines used to treat cancer (including radiation therapy).

7. have a type of enzyme deficiency called complete dihydropyrimidine dehydrogenase (DPD) deficiency.

Check with your doctor if you:

- have any other medical conditions such as heart disease, kidney disease, liver disease or any known enzyme deficiencies in particular dihydropyrimidine dehydrogenase deficiency, which can cause a life-threatening condition if DBL Fluorouracil Injection BP is used.
- take any medicines for any other condition.

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

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

Like most cytotoxic medicines fluorouracil is not recommended for use during pregnancy. It is recommended that you use an appropriate method of birth control during treatment with DBL Fluorouracil Injection BP and for at least 6 months after your last dose. Your doctor will discuss this with you. If there is any need to consider fluorouracil during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

Talk to your doctor immediately if you are breastfeeding or intend to breastfeed.

Males: tell your doctor 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 an appropriate method of birth control during treatment with DBL Fluorouracil Injection BP and for at least 3 months after your last dose. A barrier method of birth control, such as a condom, should be used. Your doctor will discuss this with you.

Previous radiation or other cancer treatment

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

Vaccinations

Tell your doctor if you are going to be vaccinated (have an injection to prevent a certain disease).

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 may interfere with DBL Fluorouracil Injection BP and affect how it works.

- allopurinol (used to treat gout)
- cimetidine (used to treat stomach ulcers)
- phenytoin (used to treat epilepsy)
- warfarin (used to prevent blood clots)
- brivudine and sorivudine (used to treat viral infections)
- metronidazole (used to treat some types of infections)
- leucovorin (folinic acid) (used together with some cancer therapy)
- levamisole, methotrexate and other cytotoxic medicines (used to treat cancer)
- thiamine (vitamin B1).

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

4. How is DBL Fluorouracil Injection BP given?

How much will be given

- Your doctor will decide what dose you will receive.
- DBL Fluorouracil Injection BP may be given alone or in combination with other drugs to treat cancer.

How long will DBL Fluorouracil Injection BP need to be given

- 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 DBL Fluorouracil Injection BP 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 too much DBL Fluorouracil Injection BP is given

DBL Fluorouracil Injection BP will be given under medical supervision so an overdose is unlikely. However, if you experience severe side effects tell your doctor or nurse immediately.

Symptoms of an overdose may include the side effects listed in Section [6. Are there any side effects?](#) but are usually of a more severe nature.

5. What should I know during treatment with DBL Fluorouracil Injection BP?

Things you should do

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.

Take precautions to reduce your risk of bleeding or infection

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.

Take precautions to protecting other people while receiving treatment with DBL Fluorouracil Injection BP

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, vomit 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.

Call your doctor immediately if you become pregnant while you are being given fluorouracil.

Remind any doctor, dentist, nurse or pharmacist you visit that you are being given DBL Fluorouracil Injection BP.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Fluorouracil Injection BP affects you.

DBL Fluorouracil Injection BP may cause dizziness, tiredness 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make dizziness or confusion worse.

Looking after your medicine

DBL Fluorouracil Injection BP is stored in a hospital which is responsible for storing and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have side effects. Some side effects may need medical attention.

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

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

Side effects	What to do
<ul style="list-style-type: none"> ● restlessness 	
<ul style="list-style-type: none"> ● yellowing of the skin or eyes ● sore mouth, mouth ulcers ● a sore rectum or anus ● loss of fingernails or toenails ● 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/or 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 	<p>Speak to your doctor <u>as soon as possible</u> if you notice any of these side effects.</p>

Side effects	What to do
<p>than normal. Avoid excessive exposure to the sun and sun lamps, wear sunscreen and protective clothing.</p> <ul style="list-style-type: none"> ● Fever ● pain, stiffness or swelling in joints ● swelling, redness, or pain near the injection site. 	
<ul style="list-style-type: none"> ● chest pain ● 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 (including bloody or black stools, blood in urine) ● severe diarrhoea ● severe abdominal pain ● severe mouth ulceration ● difficulty swallowing 	<p>Call your doctor immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● seizures, coma ● 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. 	

Tell your doctor, nurse 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. 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.

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. 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.

What DBL Fluorouracil Injection BP contains

Active ingredient (main ingredient)	fluorouracil
Other ingredients (inactive ingredients)	sodium hydroxide; water for injections

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

What DBL Fluorouracil Injection BP 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 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 2.5g/50mL, available in packs of 1 (AUST R 75832)

Who distributes DBL Fluorouracil Injection BP

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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