

DBL™ Cytarabine Injection

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 treated with DBL Cytarabine Injection?

DBL Cytarabine Injection contains the active ingredient cytarabine. DBL Cytarabine Injection is used to treat certain blood, bone marrow, and brain cancers. For more information, see Section [1. Why am I being treated with DBL Cytarabine Injection?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to DBL Cytarabine Injection 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. DBL Cytarabine Injection should not be used in pregnant women or women whose

partners are receiving treatment, and for a period after treatment stops. Women should not breastfeed when being treated with DBL Cytarabine Injection or for at least a week after treatment stops. For more information, see Section [2. What should I know before treatment with DBL Cytarabine Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Cytarabine Injection 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 Cytarabine Injection given?

DBL Cytarabine Injection can be given in a number of different ways. More instructions can be found in Section [4. How is DBL Cytarabine Injection given?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none">• Tell your doctor straight away if you experience severe side effects.• Use a reliable form of contraception during
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	<p>treatment and for a period afterwards. Tell your doctor immediately if you or your partner becomes pregnant while either of you are being treated with DBL Cytarabine Injection.</p> <ul style="list-style-type: none"> • Remind any doctor or pharmacist who are treating you that you are being treated with DBL Cytarabine Injection.
Things you should not do	<ul style="list-style-type: none"> • Do not take any other medicines, or vaccines, whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive, operate machinery or do anything else that could be dangerous until you know how DBL Cytarabine Injection affects you.
Drinking alcohol	<ul style="list-style-type: none"> • No information is available

For more information, see Section [5. What should I know during treatment with DBL Cytarabine Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects may include hot/tender/red skin or hard area under injection site; sore throat, sore mouth/mouth ulceration; anal ulcer/inflammation; diarrhoea; vomiting, nausea; constipation; sleepiness; cold hands/feet; sweating, chills, shivering; loss of appetite; aching muscles; bone pain; hair loss; itching, rash, ulceration or peeling of the skin; stomach pain; generally feeling unwell; freckling; fever; infection; yellowish skin/eyes; irregular or rapid heart rate; difficulty passing urine; headache; redness, swelling, tender palms of hands/soles of feet with thick calluses or blisters; paralysis; cough with yellow/green/bloody mucus; dizziness/light-headedness; confusion, change in mental status or personality; coordination /movement/balance problems; numbness; trouble sleeping; slurred speech; problems with vision; conjunctivitis or eye discomfort; any unusual bruising or bleeding; bluish skin/lips/nails; swelling/skin colour changes in hands/feet; severe upper or lower stomach pain; allergic reaction; shortness of breath, fast/shallow breathing, wheezing; chest pain; coma; convulsions.

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.

DBL™ Cytarabine Injection

Active ingredient(s): *cytarabine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Cytarabine Injection. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about being treated with DBL Cytarabine Injection.**

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Cytarabine Injection?

DBL Cytarabine Injection contains the active ingredient cytarabine, which is a synthetic pyrimidine nucleoside. It is a cytotoxic agent, also referred to as chemotherapy medicine. It is used to treat cancers by inhibiting DNA synthesis to kill the cancer cells and stop them from growing and multiplying.

DBL Cytarabine Injection is used to treat adults and children with:

- leukaemia which is cancer of the blood and bone marrow
- meningeal leukaemia/neoplasms, a form of brain cancer

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

Warnings

You should not be treated with DBL Cytarabine Injection if:

- you are allergic to cytarabine, or any of the ingredients listed at the end of this leaflet.

Check with your doctor if you:

- have had prior treatment with L-asparaginase
- plan to have any vaccinations
- have problems with your liver
- have problems with your kidneys
- plan to have children

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

DBL Cytarabine Injection should not be used in pregnant woman as it may be harmful to the fetus. Immediately inform your doctor if you or your partner are pregnant, or intend to become pregnant.

Women should use effective contraception during treatment with DBL Cytarabine Injection and for at least 6 months after treatment.

Men should use effective contraception during treatment with DBL Cytarabine Injection and for at least 3 months after treatment.

Talk to your doctor about the need for additional contraception while being given DBL Cytarabine Injection.

DBL Cytarabine Injection may affect male and female fertility. Check with your doctor for advice on fertility preservation before you begin treatment.

Breastfeeding

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

Do not breastfeed if you being given this medicine and for at least 1 week following the last dose of treatment.

DBL Cytarabine Injection may pass into breast milk and affect your baby.

3. What if I am taking other medicines?

Tell your doctor, nurse 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 Cytarabine Injection and affect how it works. These include:

- L-asparaginase, a medicine used to treat certain cancer
- Some other medicines used to treat cancer
- methotrexate, a medicine used to treat psoriasis, arthritis and cancer
- digoxin, a medicine used to treat heart problems
- some medicines used to treat infections, including gentamicin

- some vaccines

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

4. How is DBL Cytarabine Injection given?

How much is given

Your doctor will decide how much DBL Cytarabine Injection you should receive and the length of time for which you should receive it.

How is DBL Cytarabine Injection given

DBL Cytarabine Injection can be given alone or as part of a treatment plan with other chemotherapy medicines. It can be given in a number of different ways:

- as a single injection into a vein
- as an intravenous infusion (as a slow drip into a vein)
- as a single injection under the skin, where different places should be used for each injection
- as a single injection into the space around the spinal cord

If you use too much DBL Cytarabine Injection

DBL Cytarabine Injection is given under the close supervision of your doctor, it is very unlikely that you will receive too much. Symptoms of an overdose include: fever; muscle or bone pain; chest pain; problems breathing; conjunctivitis, eye pain or discomfort, problems with vision; vomiting, nausea; diarrhoea; severe skin rash; blood in your stool (poo); problems with balance, movement, speech or thinking. If you experience any side effects, tell your doctor or nurse immediately.

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

Things you should do

Keep all of your doctor's appointments and attend any appointments and tests as directed by your doctor, as treatment with DBL Cytarabine Injection requires your doctor to monitor your kidneys, liver and blood.

Tell your doctor straight away if you experience:

- Infection
- unusual bleeding or bruising
- loss of movement
- loss of or a change in sensation,

- loss of bowel or bladder control
- headache
- coma, stroke-like episodes
- painful, swollen joints
- severe upper or lower stomach pain, nausea, vomiting
- severe mouth ulcers
- diarrhoea (usually with blood and mucus)
- fever
- personality changes
- severe and unusual sleepiness
- coughing, difficulty breathing, wheezing
- severe shortness of breath, unusual laboured and rapid breathing, cough, chest discomfort, fast heart rate, confusion and extreme tiredness
- fatigue, chest pain, and palpitations
- severe skin rash, leading to peeling of the skin

Remind any doctor, nurse or dentist you visit that you are using DBL Cytarabine Injection.

Things you should not do

Do not take any other medicines, including vaccines, whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

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

Drinking alcohol

No information is available.

Looking after your medicine

DBL Cytarabine Injection is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of DBL Cytarabine Injection

The hospital staff will correctly dispose of any DBL Cytarabine Injection.

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 or pharmacist if you have any further questions about side effects.

Side effects	What to do
<ul style="list-style-type: none">• hot, tender and red skin at the injection site• sore mouth, mouth ulceration• anal ulcer, anal inflammation	Speak to your doctor or nurse if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> • diarrhoea, vomiting, nausea, constipation • tiredness, sleepiness • loss of appetite • aching muscles, bone pain • hair loss or thinning • itching, rash, skin ulceration, peeling of the skin • abdominal pain • painful, swollen joints • redness, swelling, burning, tender skin with thick calluses or blisters on the palms of your hands or soles of your feet • freckling • generally feeling unwell 	
<ul style="list-style-type: none"> • sore throat • fever • infection • pale or yellowish skin, yellow eyes • irregular heartbeat, rapid heart rate 	<p>Speak to your doctor or nurse as soon as possible if you notice any of these side effects.</p>

Side effects	What to do
<ul style="list-style-type: none"> • headache • sweating, chills, • shivering • dizziness or light-headedness • confusion, change in mental status or personality • coordination, movement and balance problems • numbness or loss of sensation • trouble sleeping • slurred speech • problems with vision • conjunctivitis or any pain or discomfort in the eyes • bluish skin, lips or nails • red, hard area under the skin near the injection site • swelling and skin colour changes in hands and feet • severe upper or lower stomach pain • difficulty passing urine (wee) 	

Side effects	What to do
<ul style="list-style-type: none"> ● signs of an allergic reaction such as shortness of breath, wheezing or difficulty breathing; flushing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; dizziness or light-headedness ● loss of feeling or movement ● any unusual bruising or bleeding including bleeding from your rectum (bottom) or vomiting that looks tarry or like ground coffee ● cough with yellow, green or bloody mucus ● shortness of breath, fast/ shallow breathing, wheezing ● chest pain ● coma ● convulsion 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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.

Some of these side effects (for example certain liver conditions, and blood abnormalities) can only be found when your doctor does tests from time to time to check your progress.

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 Cytarabine Injection contains

Active ingredient (main ingredient)	Cytarabine
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Other ingredients (inactive ingredients)	Hydrochloric acid Sodium hydroxide Water for injections
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Do not take this medicine if you are allergic to any of these ingredients.

Each DBL Cytarabine Injection contains cytarabine 1 g per 10 mL.

What DBL Cytarabine Injection looks like

DBL Cytarabine Injection is a clear, colourless sterile solution in a vial.

Aust R 47284, 47286

Who distributes DBL Cytarabine Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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