

DBL™ Cytarabine Injection

Cytarabine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Cytarabine Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL Cytarabine Injection is used for

Cytarabine belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine.

Cytarabine is classified as an antimetabolite. It interferes with the growth of cancer cells, which are eventually destroyed. Since the growth of normal body cells may also be affected by cytarabine, other effects may also occur (see Side Effects).

Cytarabine is most often used in combination with other medicines to treat cancer (especially leukaemias).

Ask your doctor if you have any questions about why DBL Cytarabine Injection has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you are given DBL Cytarabine Injection

When you must not be given it

DBL Cytarabine Injection should not be given to you if you have an allergy to:

- any medicine containing cytarabine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to cytarabine 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 been given cytarabine previously.

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

Your doctor can discuss with you the risks and benefits involved.

Cytarabine may cause birth defects (such as defects of the arms, legs or ears), if either the male or female is undergoing treatment with it at the time of conception, or if the female is receiving cytarabine during early pregnancy.

Women of childbearing potential should use effective contraception during treatment with Cytarabine Injection and for 6 months after the last dose.

Male patients being treated with Cytarabine Injection should use effective contraception during treatment and for 3 months after the last dose if their female partner is of child bearing potential.

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

It is not known if cytarabine passes into breast milk. Do not breastfeed while being treated with Cytarabine Injection and for at least one week after the last dose.

If you are not sure whether you should be given DBL Cytarabine Injection, talk to your doctor.

Before you are given it

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

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant, or if you are breast-feeding or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease or poor liver function
- kidney disease
- gout (high levels of uric acid in the blood)
- bone marrow suppression – a disease of the blood with a reduced number of red or white blood cells or platelets (cells involved in blood clotting, oxygen-carrying and the immune system)

- you have any type of infection.

If you have not told your doctor or pharmacist about any of the above, tell them before you start therapy with cytarabine.

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 cytarabine may interfere with each other. These include:

- any medicines which suppress your immune system
- methotrexate
- digoxin
- gentamicin
- medicines used to treat gout
- L-asparaginase
- flucytosine
- vaccines.

These medicines may be affected by DBL Cytarabine Injection or may affect how well it works. You may need

different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Do not have any immunisations (vaccinations) without your doctor's approval.

How DBL Cytarabine Injection is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much is given

The dose of cytarabine will be different for different patients.

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

DBL Cytarabine injection is often given together with other cytotoxic medicines.

How is it given

DBL Cytarabine Injection should only be given by a doctor or nurse.

DBL Cytarabine Injection can be given in a number of different ways:

- as a single injection into a vein
- as a continuous slow infusion into a vein
- as a single injection under the skin
- as a single injection into the space around the spinal cord.

Several courses of cytarabine therapy may be needed, depending on your response to treatment.

Additional treatment should not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled.

Overdose

It is unlikely that you will receive an overdose as DBL Cytarabine Injection as it is most likely to be given to you in hospital under the supervision of your doctor. However, if you are given too much DBL Cytarabine Injection, you may experience side effects listed below in the ‘Side Effects’ section, but are usually of a more severe nature.

If you experience severe side effects tell your doctor immediately or contact the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Emergency department of your nearest hospital.

You may need urgent medical attention.

While you are being given DBL Cytarabine Injection

Things you must do

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of cytarabine.

DBL Cytarabine Injection is known to be powerful at reducing the body's ability to make blood cells. Therefore, regular blood tests will be required.

Cytarabine can temporarily lower the number of white blood cells in your blood, increasing the chance of you getting an infection. It can also lower the number of platelets, which are necessary for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

- **if you can, avoid people with infections. Check with your doctor immediately if you think you are getting an infection, or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination**
- **check with your doctor immediately if you notice any unusual bleeding or bruising, black stools, blood in urine or stools or pinpoint red spots on your skin**
- **be careful when using a regular toothbrush, dental floss or toothpick. Your doctor, dentist, pharmacist or nurse may recommend other ways to clean your teeth**

and gums. Check with your doctor before having any dental work done

- **do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime**
- **be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters**
- **avoid contact sports or other situations where bruising or injury could occur.**

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL Cytarabine Injection.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines use during surgery.

If you, or your partner, become pregnant while undergoing therapy with cytarabine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful driving or operating machinery until you know how cytarabine affects you.

You may feel tired and weaker while you are receiving a course of cytarabine therapy.

While you are receiving this medicine, your doctor may want you to drink extra fluids so that you will pass more urine. This will help prevent kidney problems and keep your kidneys working well.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Cytarabine Injection.

Like other medicines, cytarabine can cause some side effects. Some of these side effects may be prevented or treated by therapy with other medicines. If side effects do occur, their severity usually depends on the dose of cytarabine you receive.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- nausea, vomiting or diarrhoea
- mouth or anal soreness or ulceration
- skin ulceration
- hair loss
- swelling and redness along a vein which is extremely tender when touched
- rash
- fever and/or chills or feeling generally unwell
- bleeding
- loss of appetite
- conjunctivitis (eye infection/inflammation)
- muscle or bone pain
- pain and irritation at the injection site.

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

- tiredness, headaches, shortness of breath, dizziness, looking pale
- mood swings or personality changes
- severe mouth ulceration and/or anal ulceration
- sore throat.

Tell your doctor immediately or go to the Emergency department of your nearest hospital if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- painful or difficult breathing
- high fever, chills, headache, confusion and rapid breathing (sepsis)
- seizures
- extreme weakness
- inability to move muscles
- chest pain

- unusual bleeding or bruising (including blood in your stools or urine)
- severe nausea, vomiting, or diarrhoea
- severe stomach pain
- painful or difficult urination
- numbness or weakness
- blurred vision or sensitive eyes
- yellowing of the skin or eyes (jaundice).

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

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

Other side effects not listed above may also occur in some people.

Some of these side effects, for example, change in liver, kidney or bone marrow function, can only be found when your doctor does tests from time to time to check your progress.

After being given DBL Cytarabine Injection

The benefits and side effects of cytarabine may take some time to occur. Therefore, even after you have finished receiving your cytarabine treatment you should tell your

doctor immediately if you notice any of the side effects listed above.

Storage

DBL Cytarabine Injection should be stored in a cool dry place and protected from light. Store at 15°C to 25°C.

Product description

What it looks like

DBL Cytarabine Injection is a clear, colourless solution. It is available in packs of single vials.

Ingredients

Active ingredients:

- Cytarabine
- Other ingredients:
- Hydrochloric acid
- Sodium hydroxide
- Water for Injections

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

Sponsor

DBL Cytarabine Injection is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

DBL Cytarabine Injection comes in a number of different strengths:

- DBL Cytarabine Injection 1g/10mL x1 ONCO-TAIN[®] vial presentation. AUST R 47284
- DBL Cytarabine Injection 2g/20mL x 1 ONCO-TAIN[®] vial presentation. AUST R 47286

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[®] = Registered trademark

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