

DBL™ Cytarabine Injection

Cytarabine (*sye-TARE-a-been*)

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 or pharmacist 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 this medicine, ask your doctor or pharmacist.

Keep this leaflet in a safe place.

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).

Your doctor may have prescribed cytarabine for another reason. Ask your doctor if you have any questions about why DBL™ Cytarabine Injection has been prescribed for you.

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 cytarabine or any of the ingredients listed at the end of this leaflet.

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.

DBL™ Cytarabine Injection should not be given to you if:

- you have a low white blood cell (WBC) count
- you have problems with blood clotting
- you have an infection

Tell your doctor if you are pregnant.

Cytarabine may affect your developing baby if you are given it during pregnancy.

It is recommended that you and your doctor discuss your need for cytarabine treatment during pregnancy, and the possible risks and benefits of using cytarabine during pregnancy.

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. It is best to use some kind of birth control while you are receiving cytarabine.

Many cancer medicines can cause infertility. Your doctor should discuss this issue with you before you begin therapy with cytarabine.

Tell your doctor if you are breastfeeding. DBL™ Cytarabine Injection should not be given to you if you are breastfeeding.

As cytarabine may cause serious side effects in a breastfed baby, breastfeeding is not recommended while you are receiving it.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- cytarabine
- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant, or if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the possible risks and benefits of using cytarabine during pregnancy or breastfeeding.

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

- liver disease
- kidney disease
- gout

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/using any other medicines, including any that you buy 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
- medicines used to treat gout
- L-asparaginase
- flucytosine

These medicines may be affected by cytarabine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor or pharmacist will advise you.

While you are being treated with cytarabine, and for about one month after you stop treatment with it, **do not have any immunisations (vaccinations) without your doctor's approval.**

Cytarabine may lower your body's resistance and there is a chance you may get the infection the immunisation is meant to prevent. In addition, other persons living in your household should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are undergoing therapy with cytarabine.

How DBL™ Cytarabine Injection is given

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 it is 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.

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

As DBL™ Cytarabine Injection is most likely to be given to you in hospital under the supervision of your doctor, it is unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital. In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

Symptoms of a cytarabine overdose include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature.

While you are being given DBL™ Cytarabine Injection

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.

Things you must do

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 become pregnant while undergoing therapy with cytarabine, tell your doctor immediately.

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

Check with your doctor, pharmacist or nurse as soon as possible if you have any problems while you are being given DBL™ Cytarabine Injection, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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.

The effects of cytarabine may take some time to occur and therefore the side effects may be delayed. It is possible that the unwanted side effects may not occur until months after DBL™ Cytarabine Injection is given.

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

While being given it

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

- severe nausea and vomiting
- severe diarrhoea
- severe mouth ulceration and/or anal ulceration
- severe abdominal pain
- sore throat
- painful or difficult urination
- chest pain
- fever
- extreme weakness

- blurred vision or sensitive eyes
- painful or difficult breathing
- personality changes
- unusual bleeding or bruising (including blood in your stools or urine)
- unconsciousness
- yellowing of the skin or eyes (jaundice)

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

- nausea and vomiting
- diarrhoea
- hair loss
- changes in skin or nail appearance
- loss of appetite
- abdominal pain
- headaches
- rash
- soreness or ulceration of the mouth
- conjunctivitis (eye infection/inflammation)
- dizziness
- weakness or tiredness
- pain and irritation at the injection site

Treatment with cytarabine may cause changes in your blood cells which may be serious. Cytarabine may also affect how your kidneys and liver work. Your doctor will arrange regular blood tests and checks to detect any changes.

Some people may get other side effects while being given cytarabine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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:

- Water for Injections

DBL™ Cytarabine Injection does not contain lactose, sucrose, gluten, 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
23 Haining Street

Te Aro
Wellington
New Zealand

DBL Cytarabine Injection comes in a number of different strengths:

- DBL™ Cytarabine Injection 1g/10mL x1 vial. AUST R 47284
- DBL™ Cytarabine Injection 2g/20mL x 1 ONCO-VIAL presentation. AUST R 47286

This leaflet was updated in: October 2013.