CYTARABINE INJECTION

Cytarabine [sye-TAYR-a-been]

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about 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 benefits and risks. Your doctor has weighed the risks of you taking Cytarabine Injection against the benefits this medicine is expected to have for you.

This medicine will be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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 Cytarabine Injection is used for

Cytarabine belongs to a group of medicines known as antineoplastics. It is used to treat cancer.

How Cytarabine Injection works

Cytarabine works by preventing the growth of cancer cells and eventually destroying them. It is used alone or in combination with other medicines to treat some cancers, particularly cancers of the blood (especially leukaemia).

Cytarabine Injection may be used to treat other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed Cytarabine Injection.

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

Use in Children

Cytarabine Injection is also used in children to treat blood cancers such as leukaemia. It is also sometimes used in combination with other medicines to treat non-Hodgkins lymphoma.

Before you are given Cytarabine Injection

When you must not be given it Do not have Cytarabine Injection 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 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.

Do not have this medicine if you are pregnant or planning to fall pregnant.

Do not have this medicine if you are breastfeeding.

It is not known if cytarabine passes into breast milk.

If you are not sure whether you should be given Cytarabine Injection, speak 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 or have had any of the following medical conditions:

- · liver disease or poor liver function
- kidney disease
- gou
- bleeding or bruising more easily than normal
- bone marrow suppression decreased levels of cells in your bloodstream including white blood cells and platelets (cells involved in the blood clotting process)
- · any sort of infection

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

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

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

Taking other medicines

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

Some medicines may be affected by 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 will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- other medicines to treat cancer such as methotrexate.
- medicines to treat bacterial infections such as gentamicin
- vaccines (injections to prevent you getting a certain disease)
- digoxin, a medicine used to treat an irregular heart beat

You may need different amounts of your medicines or you may need to take different medicines. Your doctor will advise you.

How 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.

Cytarabine is given by a slow injection into a vein or under the skin. Occasionally it may be injected directly into the fluid around the spine. Cytarabine must only be given by a doctor or nurse.

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, blood tests and whether or not other medicines are being given at the same time.

Cytarabine Injection may be given alone or in combination with other drugs.

If you are given too much (overdose)

Overdose is unlikely as Cytarabine Injection is given in hospital under the supervision of a doctor, or nurse trained to administer medicine intravenously. However, if you are given too much cytarabine, you may experience some of the effects listed under "Side effects" below.

Immediately telephone your doctor or the Poisons Information Centre (Phone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think you may have been given too much cytarabine. Do this even if there are no signs of discomfort or poisoning.

Ask your doctor if you have any concerns. Your doctor has information on how to recognise and treat an overdose.

While you are given Cytarabine Injection

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 white cell and/or platelet cell count is low, to reduce the risk of infection or bleeding:

- if you can, avoid people with infections.
 Check with your doctor 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, tarry 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, or nurse may recommend other ways to clean your teeth and gums. Check with your medical 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Cytarabine Injection.

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.

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

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

It may affect other medicines used during surgery.

If you fall pregnant while receiving this medicine, tell your doctor immediately.

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

It may interfere with the results of certain tests.

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

Your doctor may do certain 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 Injection 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 you will pass more urine. This will help prevent kidney problems and keep your kidneys working well.

Side effects

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

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

It can be difficult to tell whether side effects are the result of having Cytarabine Injection, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Ask your doctor, nurse or pharmacist to answer any questions that you may have. Do not be alarmed by this list of possible side

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

Tell your doctor if

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting or diarrhoea
- oral and anal ulcers or inflammation
- loss of appetite
- hair loss, especially of the scalp
- rasł
- fever and chills, sweats or feel generally unwell
- · muscle or bone pain
- swelling and redness along a vein which is extremely tender when touched
- conjunctivitis (itchy eyes with a discharge)
- bleeding

These are more common side effects.

Tell your doctor as soon as possible if

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

- severe nausea, vomiting or diarrhoea
- stomatitis, mouth or anal ulcers

- swelling of the face, lips or tongue, or wheezing or shortness of breath after being given cytarabine
- · sore throat
- · unusual bleeding or bruising
- chest pain or stomach pain, heartburn
- itchy red rash, hives, freckling, ulcers
- yellowing of the skin
- · infections including a cough
- · difficulty passing urine
- tiredness, headaches, shortness of breath, dizziness, looking pale
- · pain, hotness or redness at site of injection
- · mood swings or personality changes
- · numbness or weakness
- difficulty with your vision

This list includes serious side effects that may require medical attention.

Go to hospital if

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

- difficulty breathing
- seizure
- severe stomach pain

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

Tell your doctor or pharmacist if you notice anything else 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 changes in liver, kidney or bone marrow function, can only be found when your doctor does tests from time to time to check your progress.

Storage

Cytarabine Injection will be stored in the pharmacy or on the ward. It is kept in a cool dry place, protected from light, where the temperature stays between 15-25°C.

Product Description

What it looks like

Cytarabine Injection is a clear solution in a plastic vial.

Ingredients

Cytarabine Injection contains Cytarabine 20 mg/mL with Sodium Chloride in Water for Injections or Cytarabine 100 mg/mL in Water for Injections .

It does not contain a preservative.

Supplier:

Cytarabine Injection is supplied in Australia by:

Pfizer Australia Pty Ltd ABN 50 008 422 348 38-42 Wharf Road

West Ryde NSW 2114 Australia Toll Free number: 1800 675 229

It is supplied in New Zealand by:

Pfizer New Zealand Ltd PO Box 3998

Auckland, New Zealand Toll Free number: 0800 736 363

Australian registration numbers

Cytarabine Injection 100 mg in 5 mL (sterile)
 Plastic Vial:
 AUST R 11351

- Cytarabine Injection 1 g in 10 mL (sterile)
 Plastic Vial:
 AUST R 11352
- Cytarabine Injection: 2 g in 20 mL (sterile)
 Plastic Vial:
 AUST R 49285

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