

Package leaflet Information for the user

Cytarabine 100 mg/ml Solution for Injection cytarabine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cytarabine Solution for Injection is and what it is used for
2. What you need to know before you use Cytarabine Solution for Injection
3. How to use Cytarabine Solution for Injection
4. Possible side effects
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1. What Cytarabine solution for injection is and what it is used for

Cytarabine Solution for Injection is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

Cytarabine Solution for Injection is used to treat some types of leukaemia (cancer affecting the blood) and lymphomas (cancer of the lymph glands). It may be used in combination with other anti-cancer medicines.

You must talk to a doctor if you do not feel better or if you feel worse

2. What you need to know before you use Cytarabine solution for injection

Do not use Cytarabine Solution for Injection

- if you are allergic to cytarabine or any of the other ingredients of this medicine (listed in section 6)
- if the cell count in your blood report is very low due to some cause other than cancer, unless your doctor decides otherwise
- if you have had severe effects on your brain (encephalopathy) are feeling increasing difficulties in body coordination after radiation treatment or treatment with another anticancer medicine such as methotrexate
- if you are pregnant (unless your doctor considers the benefits to the mother outweigh the risks to the unborn child)
- if your cancer is not spreading (your doctor will only consider treatment with cytarabine if absolutely necessary)

Tell your doctor if you think any of the above applies to you before this medicine is used.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cytarabine Solution for Injection

Take special care with Cytarabine Solution for Injection

- if the number of cells in your blood (blood cell count) is low (your doctor will check this using blood tests)
- if you have any problems with your liver including jaundice (causes yellowing of the skin)
- if you have recently received radiotherapy or other cancer medicines or if you are due to have radiotherapy (the side effects of radiotherapy can be made worse by cytarabine treatment)
- if your bone marrow is still recovering from the effects of other medicines (your doctor will check for this using blood tests and will only consider treatment with cytarabine if absolutely necessary)
- Cytarabine strongly reduces blood cell production in the bone marrow. This can make you more prone to infection or bleeding. The blood cell numbers can continue to fall for up to a week after stopping treatment. Your doctor will test your blood regularly and examine your bone marrow if required
- Serious and sometimes life-threatening side effects can occur in the central nervous system, the bowels, the lungs or the heart especially when treated with high doses of cytarabine
- The levels of uric acid (showing that the cancer cells are destroyed) in your blood (hyperuricemia) may be high during treatment. Your doctor will tell you if you need to take any medicine to control this
- During treatment with cytarabine, administration of vaccines is not advised. If required, consult your doctor
- During treatment with cytarabine, granulocyte transfusion should be avoided as severe breathing problems have been reported. Your doctor will determine if this treatment is required

Tell your doctor if either of the above applies to you before this medicine is used. Your doctor will monitor your blood to check your liver and kidney functions and to monitor for raised uric acid levels which may occur due to breakdown of cancer cells during treatment with cytarabine.

Special care will be taken if cytarabine is to be given to a child. Cytarabine should not be used in infants.

Other medicines and Cytarabine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

Special care is needed if you are taking/using other medicines as some could interact with cytarabine.

The effectiveness of the following medicines may be reduced or increased by cytarabine:

- methotrexate (a medicine used to treat a range of cancers and some inflammatory conditions)
- digoxin or beta-acetyldigoxin tablets (heart medicine)
- gentamicin (an antibiotic)

- 5-fluorocytosine (a medicine used to treat fungal infections)
- idarubicin (a chemotherapy medicine)
- other medicines which decrease the activity of the immune system

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

Pregnancy

Avoid becoming pregnant while you or your partner is being treated with cytarabine. As there is a risk of birth defects, women of childbearing potential or their partner should use appropriate contraception methods during and up to 6 months after treatment with cytarabine to prevent pregnancy.

Contraception in women of childbearing potential

Women should always use highly effective birth-control (contraception) to prevent pregnancy during treatment and for 6 months after the last dose. Talk to your doctor about birth control methods that are right for you and your partner.

Contraception in men

Male patients with female partners of reproductive potential should always use highly effective contraception to prevent pregnancy during treatment and for 3 months after the last dose.

Breast-feeding

You should stop breast-feeding for the duration of cytarabine therapy and for at least one week after the last dose because this medicine may be harmful to infants being breast-fed.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

Cytarabine contains sodium

Cytarabine 100 mg/ml Injection contains less than 1 mmol sodium (23 mg) in each vial, that is to say essentially 'sodium-free'.

3. How to use Cytarabine solution for injection

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

This medicine may be given by injection (using a syringe) under the skin (subcutaneous) or into a vein (intravenous). It may also be given by infusion (drip) into a vein. If given as an infusion, Cytarabine Solution for Injection will be diluted first.

Cytarabine 100 mg/ml Solution for Injection must **not** be injected intrathecally (into the spine).

Recommended Dose

Your doctor will work out the correct dose of cytarabine for you and how often it must be given.

The dose will depend on your medical condition, your size and how well your liver is working. Your doctor will tell how well your liver is working using blood tests.

You will have regular blood tests after your dose of cytarabine to check for side effects. These tests may be done more often if you are elderly, as you may be more likely to get side effects. Treatment may have to be stopped if your blood cell count drops too low.

If you use more Cytarabine Solution for Injection than you should

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

If you forget to use Cytarabine Injection

Do not take a double dose to make up for a forgotten dose.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor or nursing staff immediately:

- sore mouth, particularly if you have a number of ulcers inside of the mouth
- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint. If the reaction is very severe (after high dose cytarabine), you may stop breathing and your heart may stop beating
- symptoms of an infection, e.g. fever, chills, achiness
- unexpected bleeding e.g. bleeding gums, blood in urine or vomit, unexpected bruises
- black tarry stools which may indicate bleeding in the digestive system
- severe abdominal pain (this may be a symptom of inflammation of the pancreas)
- severe chest pain and difficulty breathing (this maybe a symptom of pericarditis)
- loss of vision, loss of sense of touch, mental disturbance or loss of ability to move normally (this medicine may cause side effects to the brain and eyes which are usually reversible but may be very serious)

These are very serious side effects. You may need urgent medical attention.

The side effects of cytarabine are dependent on the dose. The digestive tract is most commonly affected, but also the blood.

Very common: may affect more than 1 in 10 people

- bone marrow suppression, low counts of pre-stages of red cells in the blood (reticulocytopenia)
- sore or itchy eyes (at high doses)
- black tarry stools which may indicate bleeding in the digestive system
- impaired liver function

- yellowing of the skin or yellowing of the whites of the eyes (jaundice)
- rash or development of raised coloured blotches
- symptoms of an infection, e.g. fever, chills, aches or soreness when swallowing
- chest pain
- skin and mucosal bleeding, irritation or severe blood infection (sepsis) at the site of injection

Common: may affect up to 1 in 10 people

- decrease in cells responsible for providing immunity, carrying oxygen around the body and for normal blood clotting shown as a reduction in the amount of red and white cells and platelets in the blood or abnormal red blood cells, anaemia, shortness of breath, unexpected bleeding e.g. bleeding gums, blood in urine or vomit, unexpected bruises
- abnormal blood cells (megaloblastosis)
- loss of appetite
- reduced consciousness, speaking difficulties, abnormal eye movements (nystagmus), dizziness, inflammation of a nerve or part of the nervous system, damage to nerve tissues and pain (at high doses)
- reversible effects on the eyes such as sore eyes with bleeding (haemorrhagic conjunctivitis), vision disturbance, sensitivity to light (photophobia), watery or burning eyes and inflammation of the surface of the eye (cornea) (keratitis)
- swallowing difficulties
- feeling or being sick, diarrhoea, sores or ulcers in the mouth or anus (back passage), mild pain in the abdomen
- reversible effects on the liver such as increased enzyme levels
- reversible effects to the skin such as reddening (erythema), blistering, rash, hives, blood vessel inflammation (vasculitis)
- hair loss (at high doses)
- impaired / disturbed kidney function, problems passing urine
- high levels of uric acid in your blood due to the breakdown of cancer cells during treatment with cytarabine (your doctor will monitor for this)
- fever
- blood clots causing inflammation at the site of injection

Uncommon: may affect up to 1 in 100 people

- whole body infection (sepsis) seen as a fever, vomiting, confusion, dizziness, chills
- lung infection
- headache
- numbness or weakness of the arms and legs, paralysis of the legs and lower body when cytarabine is given into the space surrounding the spinal cord (intrathecal)
- inflammation of the sac that surrounds the heart
- shortness of breath
- sore throat
- inflammation of the food pipe (oesophagus), ulcers in the food-pipe
- bowel cysts, severe bowel inflammation, serious infection of the membrane that lines the abdomen (peritonitis)
- brown/black spots on the skin (lentigo), ulceration of the skin, itching
- painful redness and blistering on the hands and the soles of the feet (at high doses)
- joint and muscle pain
- inflammation at the site of injection

Very rare: may affect up to 1 in 10,000 people

- severe hypersensitivity (severe allergy)
- severe spinal cord damage (even leading to Leigh's disease (necrotising encephalopathy), quadriplegia (total or partial loss of movement in limbs and body), paralysis and blindness)
- irregular heart beat (arrhythmia)
- inflammation of the pancreas

Not known: frequency cannot be estimated from the available data

- low counts of pre-stages of red cells in the blood (reticulocytopenia)
- dizziness, inflammation of a nerve or part of the nervous system, damage to nerve tissues and pain
- sore or itchy eyes
- black tarry stools which may indicate bleeding in the digestive system
- impaired liver function
- yellowing of the skin or yellowing of the whites of the eyes (jaundice)
- pigmented spots on the skin (freckles)
- redness, pain or swelling of the ears that may occur during or shortly after cytarabine treatment (known as "Ara-C ears" or auricular erythema)
- inflammation of sweat glands, sometimes causing tender red patches on the skin (called neutrophilic eccrine hidradenitis)
- kidneys may not work properly
- lack of periods and low sperm count (Amenorrhoea and azoospermia)
- chest pain
- irritation or infection at the site of injection
- bleeding of the lining of the mouth
- isolated damage to the nervous system has been reported
- slower heartbeat

The side effects on the digestive tract are less if cytarabine is given by infusion rather than by bolus injection.

Your doctor may prescribe local steroids (anti-inflammatory medicines) to reduce effects on the eyes such as sore eyes with bleeding (haemorrhagic conjunctivitis).

Cytarabine may lead to changes in your blood cells. Your doctor will take blood samples to monitor for these and also to check how well your liver and kidneys are working.

Sometimes the following side effects can occur together, usually 6-12 hours after receiving cytarabine:

- feeling generally unwell with a high temperature
- pain in bone muscle and occasionally the chest
- blistering rash
- sore eyes
- feeling "out of sorts"

This is known as 'Cytarabine syndrome' and can be treated. If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

Side effects after high dose Cytarabine treatment:

Severe and at times fatal side effects on the blood, eyes, lungs, nervous system, liver, digestive or genital system have been reported after using experimental dose schedules. The side effects have included severe bone marrow suppression, reversible effects on the cornea (surface of the eye), effects on the brain (usually reversible), drowsiness and convulsion, ulcers in the digestive system which may lead to infection of your abdominal lining (peritonitis), inflammation of the pancreas, liver abscess or enlargement, blood clots in the vein in the liver, blood infection, fluid in the lungs, absence of menstrual periods in women or complete lack of sperm in the ejaculate in men, heart muscle disease or abnormal muscle breakdown, which may lead to kidney problems (rhabdomyolysis).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cytarabine solution for injection

Keep this medicine out of the sight and reach of children.

Do not use Cytarabine Solution for Injection if you notice the solution is not clear and colourless.

Expiry

Do not use this medicine after the expiry date which is stated on the vial and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Storage

Do not store above 25°C. Keep container in the outer carton in order to protect from light. Do not refrigerate or freeze.

Chemical and physical in-use stability has demonstrated that the product is stable for 14 days at 20-21°C.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

6. Contents of the pack and other information

What Cytarabine Solution for Injection contains

The active substance is cytarabine. Each millilitre (ml) of solution contains 100 milligrams (mg) of cytarabine. The other ingredients are Water for Injections, Hydrochloric Acid and Sodium Hydroxide.

What Cytarabine Solution for Injection looks like and contents of the pack

Cytarabine Solution for Injection is a clear, colourless solution for injection which comes in glass containers called vials.

It may be supplied in packs containing:

100 mg/1 ml vials: Clear, conventional or ONCO-TAIN™, Type I glass vials with rubber stopper. Packs of 5 vials.

1 g/10 ml vials: Clear, conventional or ONCO-TAIN™, Type I glass vials with rubber stopper. Single vial packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road
Dublin 4
D04 K7N3
Ireland

Manufacturer:

Pfizer Service Company BV
Hermeslaan 11
1932 Zaventem
Belgium

This leaflet was last approved in 06/2026.

Cytarabine 100 mg/ml Solution for Injection

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Cytarabine 100 mg/ml Solution for Injection should not be administered by the intrathecal route due to the slight hypertonicity of this formulation.

Incompatibilities

Solutions of cytarabine have been reported to be incompatible with various drugs, i.e. carbenicillin sodium, cephalothin sodium, fluorouracil, gentamicin sulphate, heparin sodium, hydrocortisone sodium succinate, insulin-regular, methylprednisolone sodium succinate, nafacillin sodium, oxacillin sodium, penicillin G sodium. However, the incompatibility depends on several factors (e.g. concentrations of the drug, specific diluents used, resulting pH, temperature). Specialised references should be consulted for specific compatibility information.

Use and handling

Do not refrigerate or freeze.

Cytarabine 100 mg/ml Solution for Injection is a ready to use injection but it can be diluted with Sterile Water for Injections BP, Glucose Intravenous Infusion BP or Sodium Chloride Intravenous Infusion BP. Chemical and physical in-use stability has demonstrated that the product is stable for 14 days at 20-21°C.

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user. Do not refrigerate or freeze.

If a precipitate has formed as a result of exposure to low temperature, re-dissolve by warming up to 55°C for no longer than 30 minutes and shake until the precipitate has dissolved. Allow to cool prior to use.

Use immediately following warming and cooling of the vial. Further storage is not recommended after warming.