

Package leaflet Information for the user

Cytarabine 100 mg/ml 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cytarabine Injection is and what it is used for
2. What you need to know before you use Cytarabine Injection
3. How to use Cytarabine Injection
4. Possible side effects
5. How to store Cytarabine Injection
6. Contents of the pack and other information

1. What Cytarabine Injection is and what it is used for

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

Cytarabine 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 Injection

Do not use Cytarabine Injection

- if you are allergic to cytarabine or any of the other ingredients of this medicine (listed in section 6)
- if your blood cell count (number of cells in your blood) is very low due to some cause other than cancer (unless your doctor decides the benefits of treatment outweigh the risks)
- if you have had severe effects on your brain (encephalopathy) 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)

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 Injection

Take special care with Cytarabine Injection

- if your blood cell count is low
- if you have any problems with your liver including jaundice (causes yellowing of the skin)
- if you have recently received cancer medicine treatment or radiotherapy or if you are due to have radiotherapy (the side effects of radiotherapy can be made worse by cytarabine treatment)
- cytarabine strongly reduces blood cell production in the bone marrow and your 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
- if your bone marrow is still recovering from the effects of other medicines (your doctor will only consider treatment with cytarabine if absolutely necessary)
- 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 certain 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 blood cell count, your liver and kidney functions and to monitor for raised uric acid levels.

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 Injection

Tell your doctor if you are using, have recently used or might use 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:

- digoxin or beta-acetyl digoxin tablets (heart medicine)
- gentamicin (an antibiotic)
- 5-fluorocytosine (a medicine used to treat fungal infections)
- 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

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.

You should stop breast-feeding before starting treatment with cytarabine 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 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 Injection will be diluted first.

Cytarabine 100 mg/ml 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 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.

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
- symptoms of an infection, e.g. fever, chills, aches or soreness when swallowing
- 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 pain in the chest and difficulty breathing (this maybe a symptom of pericarditis)
- severe pain in the abdomen (this may be a symptom of inflammation of the pancreas)
- 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 serious side effects. You may need urgent medical attention.

If you experience any of the following tell your doctor as soon as possible:

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

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
- loss of appetite
- 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)
- reduced consciousness, speaking difficulties, abnormal eye movements (nystagmus)
- 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)
- 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
- impaired / disturbed kidney function, problems passing urine
- 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
- joint and muscle pain
- inflammation at the site of injection

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

- irregular heart beat (arrhythmia)

- redness and itchy bumps on hands or legs, associated with inflammation of the sweat glands

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)
- skin rash, pigmented spots on the skin (freckles), skin bleeding
- 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
- 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
- rash
- sore eyes

This is known as ‘cytarabine syndrome’ and it can be treated. If you experience these side effects please tell your doctor or nurse as soon as possible.

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 gets 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:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cytarabine Injection

Keep this medicine out of the reach and sight of children

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 the vial in the outer carton in order to protect from light.

Do not refrigerate or freeze.

6. Contents of the pack and other information

What Cytarabine 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 Injection looks like and contents of the pack

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

It may be supplied in packs containing:

- 1, 5, 10 or 20 x 100 mg/1 ml vials
- 1, 5, 10 or 20 x 500 mg/5 ml vials
- 1, 5, 10 or 20 x 1 g/10 ml vials
- 1, 5, 10 or 20 x 2 g/20 ml vials

Not all packs may be marketed.

Marketing Authorisation Holder

Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road

Tadworth
Surrey
KT20 7NS
UK

Manufacturer

Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

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Cytarabine 100 mg/ml 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 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 sulfate, 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 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 been demonstrated for 7 days at room temperature.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours unless dilution has taken place in controlled and validated aseptic conditions.

Prior to use, vials of Cytarabine 100mg/ml Injection must be warmed to 55°C, for 30 minutes, with adequate shaking, and allowed to cool to room temperature.