

Patient leaflet: Information for the user

Cytarabine 20mg/ml and 100mg/ml Solution for infusion or injection (Cytarabine)

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Cytarabine is and what it is used for

- Cytarabine is used in adults and children.
- This medicine contains cytarabine, which is one of a group of the medicines known as cytotoxics. These medicines are used in the treatment of acute leukaemias (cancer of blood where you have too many white blood cells). Cytarabine interferes with the growth of cancer cells, which are eventually destroyed.
- Cytarabine is also used for the induction and maintenance of remission of leukaemia.
- Remission induction is an intensive treatment to force leukaemia into retreat. When it works, the balance of cells in your blood becomes more normal and your health improves. This relatively healthy spell is called a remission.
- Maintenance therapy is a milder treatment to make your remission last as long as possible. Quite low doses of Cytarabine are used to keep the leukaemia under control and stop it flaring up again.

You should consult your doctor if you are unsure why you have been given Cytarabine, if you do not feel better or if you feel worse.

2. What you need to know before you are given Cytarabine

Do not use Cytarabine:

- If you are allergic (hypersensitive) to cytarabine, or any of the other ingredients of this medicine (listed in section 6).

- If you are already taking medicines that have caused you to have a low blood count caused by suppression of your bone marrow. Your doctor might not give this medicine if you have a non-malignant disease, except for immunosuppression.

Warnings and precautions

Tell your doctor if:

- your liver is not working properly. This will help your doctor decide if Cytarabine is suitable for you.
- you have had or are due to have any vaccination including a live or live-attenuated vaccination.
- you are given Cytarabine in combination with methotrexate administered through your spine, because cases of headache, paralysis, coma and stroke-like symptoms have been reported in children and young adults given intravenous Cytarabine in combination with intrathecal methotrexate.

Other medicines and Cytarabine

Tell your doctor or pharmacist if you are:

- given medicines containing 5-Fluorocytosine (a medicine used to treat fungal infections).
- taking medicines containing digitoxin or beta-acetyldigoxin which are used to treat certain heart conditions.
- taking gentamicin (an antibiotic used to treat bacterial infections).
- given medicines containing cyclophosphamide, vincristine and prednisone which are used in cancer treatment programmes.
- Taking, have recently taken or might take any other medicines, even those not prescribed.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine because Cytarabine may cause birth defects. Avoid becoming pregnant while you or your partner is being treated with Cytarabine. If you are sexually active, you are advised to use effective birth control to prevent pregnancy during treatment, whether you are male or female.

Breast-feeding

You should stop breast-feeding before starting treatment with Cytarabine because this medicine may be harmful to infants being breast-fed.

Driving and using machines

If you feel unwell following treatment with Cytarabine you should avoid driving or using machinery.

Cytarabine contains sodium

Cytarabine 100 mg/5 ml (20 mg/ml), 1000 mg/10ml (100 mg/ml), 2000 mg/20ml (100 mg/ml) solution for infusion or injection contains less than 1 mmol sodium (23 mg) in each vial, that is to say essentially 'sodium-free'.

Cytarabine 500 mg/25 ml (20 mg/ml) Solution for injection contains 66.75 mg of sodium (main component of cooking/table salt) in each vial. This is equivalent to 3.34% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Cytarabine is given to you

Cytarabine will be given to you by infusion into a vein (through a 'drip') or by injection under the direction of specialists in hospital. Your doctor will decide what dose to give and the number of days' treatment you will receive depending on your condition.

The dose of Cytarabine will be decided by your doctor based on your condition being treated for, whether you are in induction or maintenance therapy and your body surface area. Your body weight and height will be used to calculate your body surface area.

Regular Check-ups

During treatment you will need regular checks including blood tests. Your doctor will tell you how often this should be done. He/she will be making regular checks of:

- your blood- to check for low blood cell counts that may need treatment.
- your liver – using blood tests – to check that Cytarabine is not affecting the way it functions in a harmful way.
- your kidneys – using blood tests – to check that Cytarabine is not affecting the way it functions in a harmful way.
- Blood uric acid levels - Cytarabine may increase uric acid levels in the blood. Another medicine may be given if your uric acid levels are too high.

If you receive high doses of Cytarabine:

High doses can worsen side effects like sores in the mouth or may decrease the number of white blood cells and platelets (these help the blood to clot) in the blood. Should this happen, you may need antibiotics or blood transfusions. Mouth ulcers can be treated to make them less uncomfortable as they heal.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all cytotoxic medicines, this medicine causes side effects, although not everybody gets them.

Tell your doctor or nursing staff who will be monitoring you during this time

immediately, if you suffer from the following symptoms after taking this medicine:

- An allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- You are feeling tired and lethargic.
- You have flu like symptoms e.g. raised temperature or fever and chills.
- You bruise more easily or bleed more than usual if you hurt yourself. These are the symptoms of **low numbers of blood cells**. **Tell your doctor or nursing staff immediately** if you experience these symptoms.

Other side effects that may occur are:

If any of these side effects gets serious please **tell your doctor or nursing staff immediately**.

Very common: may affect more than 1 in 10 people

- Pneumonia, infection (which can become serious and lead to organ failure),

- Insufficient production or decrease in numbers of red blood cells, white blood cells or platelets.
- Inflammation or appearance of sores in the mouth, lips, or on the anus (back passage), feeling sick, being sick, diarrhoea, abdominal pain
- Liver damage
- Hair loss is common and may be quite severe. Hair normally re-grows when your treatment course ends. Skin rash
- Cytarabine syndrome, sometimes the following side effects can happen together 6 to 12 hours after receiving Cytarabine. Feeling generally unwell with a high temperature, pain in bone, muscle and sometimes the chest, blistering rash, sore eyes. This is called "Cytarabine Syndrome" and can be treated.
- Feeling hot and feverish
- Abnormal bone marrow results from a biopsy, or blood results from a smear test

Common: may affect up to 1 in 10 people

- Ulceration on your skin

Not known: frequency cannot be estimated from the available data

- You may get an infection, including infection or inflammation at the site of your injection
- Loss of appetite
- Headaches or feeling dizzy, feeling of pins and needles, shaking and fits, drowsiness
- Conjunctivitis
- Pericarditis (inflammation of the covering of the heart)
- Slower than usual heart rate or heartbeat
- Inflammation to your veins (caused by a blood clot)
- Shortness of breath, sore throat, pain or difficulty swallowing
- Pancreatitis (pain in the upper abdomen) often accompanied by feeling sick or vomiting, inflammation or ulcers in the gullet, causing heartburn may make you feel sick,
- Jaundice (seen as yellowing of the skin and whites of the eye)
- Skin redness (similar to sunburn), pain and numbness in joints, fingers, toes or face, swelling of the abdomen, legs, ankles and feet, a sensation of tingling or burning, tenderness and tightness of the skin, thick calluses on the palms and hands, itchy skin rash, itching or increased freckles
- Difficulty or pain when passing urine. Blood in your urine and impaired kidney function

The following side effects have been reported with high dose therapy:

Very common: may affect more than 1 in 10 people

- Paralysis caused by cerebral disorder, experience problems in walking, speech problems, involuntary muscle movement caused by cerebellar disorder, tiredness, weakness, fainting
- Eye infection, irritation, pain and blurred vision, visual loss
- Short or stabbing chest pain, build-up of fluid in the lungs

Common: may affect up to 1 in 10 people

- Peeling of the skin
- Infection and inflammation of the intestines, most common in babies

Not known: Frequency cannot be estimated from the available data

- A pus-filled mass inside the liver
- Changes in your personality
- Coma, convulsions, poor balance caused by damage to nerves
- Fast heartbeat, reduced function of the heart, shortness of breath, dizziness, swelling of legs, ankles, feet and veins in the neck (cardiomyopathy), which can be fatal
- Slower than usual heart rate or heartbeat
- Blood in vomiting or in stools (gastrointestinal necrosis or ulcer), stomach pain or tenderness (peritonitis)

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 the Yellow Card Scheme at: 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

Keep out of the sight and reach of children.

Hospital staff will store your medicine safely. The unopened vials should be stored in the original container between 15°C and 25 °C until ready for use.

Cytarabine should not be used after the expiry date which is stated on the vial label and carton after EXP. 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.

6. Contents of the pack and other information

What Cytarabine contains

The active ingredient is cytarabine.

The other ingredients in Cytarabine 20mg/ml are hydrochloric acid, sodium hydroxide, nitrogen, water for injections and sodium chloride.

The other ingredients in Cytarabine 100mg/ml are hydrochloric acid, sodium hydroxide, nitrogen and water for injections.

What Cytarabine looks like and contents of the pack

Cytarabine is a solution available in two strengths: 20mg/ml and 100mg/ml.

Cytarabine containing 20mg/ml is supplied in plastic vials containing 100mg (5ml) or 500mg (25ml).

Cytarabine containing 100mg/ml is supplied in plastic vials 1000mg (10ml) or 2000mg (20ml).

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ
United Kingdom

Manufacturer:

Pfizer Service Company BVBA
10 Hoge Wei
1930 Zaventem
Belgium

Company Contact Address:

For further information on your medicine contact Medical Information at Pfizer Limited,
Walton Oaks, Tadworth, Surrey, Tel: 01304 616161.

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