PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CYTOSAR® 100 mg Powder for solution for injection

CYTOSAR® 500 mg Powder for solution for injection

Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v

Cytarabine

Sugar free

Read all of this leaflet carefully before you are given CYTOSAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CYTOSAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What CYTOSAR is and what it is used for

CYTOSAR is used alone or in combination with other anti-cancer medicines in the treatment of patients with certain types of leukaemia (cancer of the blood) and lymphomas (cancer of the lymph glands).

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

You should not be administered CYTOSAR:

- if you are hypersensitive (allergic) to cytarabine or to any of the other ingredients of CYTOSAR (listed in section 6)
- if you have a low blood count caused by suppression of your bone marrow
- if you have had or are due to have a vaccination
- if you are pregnant or breastfeeding your baby
- through an injection into the spine. The product (diluent) that CYTOSAR has to be mixed with upon administration contains benzyl alcohol which can cause harmful side effects. This diluent should not be used in newborn babies (including prematurely born babies) as it can cause abnormal breathing and multiple-organ system failure.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you have a large reduction of white blood cells, blood platelets or other blood cell components (bone marrow suppression). Your doctor will perform a blood count regularly to determine whether you should continue to be treated with CYTOSAR.
- as anaphylactic reactions (severe allergic reactions) may occur.
- as serious and sometimes life-threatening side effects can occur in the central nervous system, the bowels, the lungs or the heart
- if you have any liver and/or kidney problems. Your doctor will monitor your liver and kidney function during treatment.
- if you are given CYTOSAR in combination with methotrexate (medicine used to treat a type of cancer) administered through your spine, as cases of headache, paralysis, coma and stroke-like symptoms have been reported in children and young adults when used in combination.
- if your levels of uric acid become increased (as a result of dying cancer cells). Your doctor will monitor this and may prescribe medicine to control this.

Other medicines and CYTOSAR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Other medicines may affect the way in which CYTOSAR works. You should therefore inform your doctor if you are taking any of the following medicines:

- Digoxin (used to treat certain heart conditions).
- Gentamicin and/or amikacin (an antibiotic).
- Fluorocytosine (a medicine used to treat fungal infections).
- Methotrexate (used to treat certain cancers and rheumatoid arthritis).
- Daunorubicin and thioguanine (used to treat certain cancers).
- Allopurinol, colchicine, probenecid or sulfinpyrazone (used to treat gout).

You may need different amounts of your medicines or you may need to take different medicines as advised by your doctor.

Pregnancy and breastfeeding

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 CYTOSAR because it may cause birth defects.

The use of CYTOSAR is contraindicated during pregnancy or while a mother is breastfeeding her baby.

Avoid becoming pregnant while you or your partner is being treated with CYTOSAR.

If you are sexually active, you should use highly effective birth control to prevent pregnancy during treatment, whether you are male or female. You should continue using contraception up to 6 months following the last administered dose of CYTOSAR.

You should stop breastfeeding before starting treatment with CYTOSAR because it may be harmful to your baby.

Driving and using machines

Confusion, headaches, drowsiness, dizziness, having fits, difficulty with movement or balance, and blurred vision may occur with CYTOSAR therapy. This can interfere with your ability to drive or operate any tools or machines safely.

It is not always possible to predict to what extent CYTOSAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CYTOSAR affects them.

CYTOSAR contains benzyl alcohol

The diluent solution used to reconstitute CYTOSAR contains the preservative benzyl alcohol which has been associated with serious side effects, including the “gasping syndrome” (breathing problems), and death in children and babies. The amount of benzyl alcohol required to cause this effect is not known but depends on the amount given and your body’s ability to process the toxin. The toxic effect is more likely in premature and/or low birth weight babies.

Your doctor will utilise an alternative diluent should you require high doses of CYTOSAR or if it will be injected into the spinal cord (intrathecal injection).

3. How to receive CYTOSAR

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself CYTOSAR. It will be given to you by a person who is qualified to do so.

CYTOSAR is given by injection or drip (infusion) into a vein or by injection under the skin. Occasionally it may be injected directly into the fluid around the spine.

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 size, age, blood tests and whether or not other medicines are being given at the same time.

CYTOSAR may be given alone or in combination with other medicines.
If you have the impression that the effect of CYTOSAR is too strong or too weak, tell your doctor or health care provider.

If you receive more CYTOSAR than you should

Since a healthcare professional will administer CYTOSAR, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive CYTOSAR

Since a health care provider will administer CYTOSAR, it is unlikely that the dose will be missed.

4. Possible side effects

CYTOSAR can have side effects.

Not all side effects reported for CYTOSAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CYTOSAR, please consult your health care provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Confusion, rapid breathing, increased heart rate, high or low body temperature (the presence of these symptoms may be due to blood poisoning)
- Fever, chills or other signs of infection
- Coughing, high temperature, sweating, shivering, green/yellow/dark coloured phlegm and breathlessness (these are signs of pneumonia)
- Signs of being hypersensitive (allergic) to CYTOSAR – this may include rash, itching, swelling of the face, lips, tongue or other parts of the body, wheezing or trouble breathing
- Difficulty in speaking, seeing, hearing, swallowing, problems with coordination, feeling drowsy
- Having fits
- Severe pain in your stomach (this may be due to inflammation of the pancreas)
- Yellowing of the skin and/or whites of the eyes (due to jaundice)

- Eye pain, blurred vision, loss of vision
- Severe shortness of breath, rapid/shallow breathing, tiredness, confusion, feeling faint (due to acute respiratory distress syndrome)
- Breathlessness, coughing, wheezing, coughing up blood, sweating, leg swelling, abnormal heart rate (due to fluid in the lungs)
- Signs of bleeding which include any bleeding or bruising, black or tar-like stools or being sick and bringing up blood or 'coffee-coloured granules'

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Bone marrow failure, decrease in numbers of red blood cells, white blood cells or platelets. These may cause tiredness, fever or increased risk of bleeding
- Inflammation or appearance of sores in the mouth, lips, or on the anus (back passage), feeling and/or being sick, diarrhoea, stomach pain
- Abnormal liver function (may cause yellowing of the skin and/or whites of the eyes)
- Hair loss, rash, skin ulcers
- Feeling generally unwell with a high temperature, pain in the bone, muscle and/or chest, eye infection, blistering rash (collectively this is known as 'Cytarabine Syndrome' and may occur 6 to 12 hours after the start of your treatment)
- Fever
- Abnormal results of a bone marrow biopsy and/or blood smear test (tests performed by your doctor)

Less frequent side effects:

- Infection, pain and/or swelling at the site of injection

- Loss of appetite
- Headaches or feeling dizzy, feeling of pins and needles, shaking and fits, drowsiness (these may be due to damage to nervous tissue or swelling of the nerves)
- Slower heartbeat
- Eye infection (conjunctivitis)
- Inflammation of the covering of the heart
- Swelling of the veins (caused by a blood clot)
- Shortness of breath and rapid breathing, cough, decreased exercise tolerance, chest pain, drowsiness, extreme tiredness, restlessness, confusion, muscle fatigue and general weakness
- Inflammation or ulcers in the gullet
- Reddening, swelling and numbness of the palms of the hands and feet, redness or itchy bumps on your skin, itching, increased freckles

- Reduced kidney function, difficulty passing urine
- Chest pain

Side effects reported with high dose therapy:

Frequent side effects:

- Inflammation of the eye
- Severe swelling of the colon (large intestine)
- Peeling of the skin

Less frequent side effects:

- Liver abscess
- Personality change
- Becoming unconscious (coma), muscle weakness, muscle twitching, pins and needles, decrease in touch sensation of the hands and feet
- Thickening/hardening of the heart muscle
- Blood in vomit or in stools (gastrointestinal necrosis or ulcer), stomach pain or tenderness (peritonitis)

Side effects reported with intrathecal injection (into your spine):

Most frequently reported side effects:

- Feeling sick
- Being sick
- Having a fever

Less frequent side effects:

- Paralysis (loss of movement) of the legs and lower body
- Difficulty with balance, speech and swallowing

- Fits
- Damage to nervous tissue
- In rare cases, blindness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CYTOSAR.

5. How to store CYTOSAR

- Store all medicines out of reach of children.
- CYTOSAR will be stored in the pharmacy or ward under the following conditions:
  - Store at room temperature between 15 °C and 30 °C.
  - Once reconstituted, store at room temperature between 15 °C and 30 °C and use within 48 hours.
  - Discard any solution in which a slight haze develops.

6. Contents of the pack and other information

What CYTOSAR contains

The active substance in CYTOSAR is cytarabine.

CYTOSAR 100 mg contains 100 mg cytarabine per vial.

CYTOSAR 500 mg contains 500 mg cytarabine per vial.

CYTOSAR is packed with Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v and must be reconstituted before use.

One 5 mL ampoule of Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v contains 45 mg benzyl alcohol.

One 10 mL ampoule of Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v contains 90 mg benzyl alcohol.

THE DILUENT CONTAINING BENZYL ALCOHOL SHOULD NOT BE USED FOR INJECTION INTO THE SPINE (INTRATHECAL USE) OR FOR HIGH DOSE THERAPY.

The other ingredients are hydrochloric acid and/or sodium hydroxide for pH adjustment.

Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v contains water for injection and benzyl alcohol (0,9 % m/v).

What CYTOSAR looks like and contents of the pack

CYTOSAR is available as a freeze-dried preparation.

CYTOSAR 100 mg: 100 mg vial plus 5 mL water for injection (with benzyl alcohol 0,9 % m/v).

CYTOSAR 500 mg: 500 mg vial plus 10 mL water for injection (with benzyl alcohol 0,9 % m/v).

CYTOSAR 100 mg and 500 mg are in multidose vials.

Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v is available in ampoules of 5 mL and 10 mL.

Holder of Certificate of Registration

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CYTOSAR 500 mg: T/26/47

Bacteriostatic water for injection plus benzyl alcohol 0,9 % m/v: H/34/60