PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CYTARABINE 100 mg/1 mL FRESENIUS Solution for infusion or injection

CYTARABINE 500 mg/5 mL FRESENIUS Solution for infusion or injection

CYTARABINE 1 g/10 mL FRESENIUS Solution for infusion or injection

CYTARABINE 2 g/20 mL FRESENIUS Solution for infusion or injection

Cytarabine

Sugar free

Read all of this leaflet carefully before you are given CYTARABINE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

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

1. What CYTARABINE FRESENIUS is and what it is used for

- **CYTARABINE FRESENIUS** contains the active ingredient cytarabine, which is one of a group of medicines known as cytotoxics. **CYTARABINE FRESENIUS** interferes with the growth of cancer cells, which are eventually destroyed.

- **CYTARABINE FRESENIUS** is used for the treatment of certain types of leukaemias (cancer of blood where you have too many white blood cells) and certain types of lymphomas cancer of the lymph glands). Cytarabine is used in adults and children.
- **CYTARABINE FRESENIUS** may be used alone or in combination with other cytotoxic medicines.
- You should consult your doctor if you are unsure why you have been given **CYTARABINE FRESENIUS**, if you do not feel better or if you feel worse.

2. What you need to know before you are given CYTARABINE FRESENIUS

CYTARABINE FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to cytarabine or any of the other ingredients of **CYTARABINE FRESENIUS** (listed in section 6).
- if you have a low blood count caused by suppression of your bone marrow.

Warnings and precautions

Only a doctor or healthcare provider experienced in cancer chemotherapy should provide you with treatment.

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with **CYTARABINE FRESENIUS**:

- if the number of cells in your blood (blood cell count) is low (your doctor will check this using blood tests). Your treatment should be altered or stopped if your blood tests indicate that your cell count is too low.
- 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 FRESENIUS** if absolutely necessary).
- serious and sometimes life-threatening allergic reactions can occur.
- complications from infection and bleeding can occur.
- 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 FRESENIUS.**
- serious reactions that may occur when treated high doses of **CYTARABINE FRESENIUS** such as

damage to the eye; loss of function in parts of the brain; sleepiness; sudden and irregular movement of the body; severe gastrointestinal inflammation, sever liver infection and abscess, and build up of water in the lungs.

- high doses of cytarabine, as in **CYTARABINE FRESENIUS** is associated with nerve damage in adult patients with acute non-lymphocytic leukemia.
- abdominal tenderness, inflammation of the colon with blood in stools and reduced number of blood cells have occurred in patients treated with conventional doses of cytarabine in combination with other medicines.
- if your liver, kidney or pancreas is not functioning properly (your doctor will check this using medical tests). This will help your doctor decide if **CYTARABINE FRESENIUS** treatment is suitable for you.
- the levels of uric acid (showing that the cancer cells are destroyed) in your blood may be high (called hyperuricaemia) during treatment. Your doctor will tell you if you need to take any medicine to control this.
- inflammation of the pancreas may be caused.
- if you have had or are due to have any vaccination including a live or live- attenuated (weakened) vaccination.
- serious toxic effect of Cytarabine, as in **CYTARABINE FRESENIUS**, is that the bone marrow makes less blood cells.
- less serious toxic effects include nausea, vomiting, diarrhoea, stomach pain, mouth sores and liver failure.

Children

Special care will be taken if **CYTARABINE FRESENIUS** is to be given to a child.

Cytarabine should not be used in infants.

Other medicines and CYTARABINE FRESENIUS

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

Tell your healthcare provider if you are:

- given medicines containing 5-Fluorocytosine (used to treat fungal infections), as treatment with it

will not be effective.

- taking medicines containing digoxin (used to treat certain heart conditions), as the blood level of this medicine may be altered.
- given gentamicin (used to treat bacterial infections), as the antibacterial effect may be diminished.
- methotrexate (used to treat a range of cancers and some inflammatory conditions). Cases of headache, paralysis, coma and stroke-like symptoms have been reported in children and young adults given intravenous **CYTARABINE FRESENIUS** in combination with intrathecal (into the spine) methotrexate.

CYTARABINE FRESENIUS with food, drink and alcohol

There are no known interactions. **CYTARABINE FRESENIUS** can be given irrespective of whether food is taken or not.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

Avoid becoming pregnant while you or your partner is being treated with **CYTARABINE FRESENIUS**. 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 FRESENIUS** to prevent pregnancy.

You should stop breastfeeding before starting treatment with **CYTARABINE FRESENIUS** because this medicine may be harmful to infants being breastfed.

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 FRESENIUS contains hydrochloric acid, sodium hydroxide and water for

injections

Sodium: This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How CYTARABINE FRESENIUS is given to you

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

You will not be expected to give yourself **CYTARABINE FRESENIUS**. It will be given to you by a person who is qualified to do so. **CYTARABINE FRESENIUS** 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 FRESENIUS** will be diluted first.

Recommended Dose

Your doctor will decide what dose to give and the number of days' and how long your treatment with **CYTARABINE FRESENIUS** will last.

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 have the impression that the effect of **CYTARABINE FRESENIUS** is too strong or too weak, tell your doctor or pharmacist.

If you receive more CYTARABINE FRESENIUS than you should

Since a healthcare provider will administer **CYTARABINE FRESENIUS**, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a CYTARABINE FRESENIUS dose is forgotten

Since a healthcare provider will administer **CYTARABINE FRESENIUS**, it is unlikely that the dose will be missed.

4. Possible side effects

CYTARABINE FRESENIUS can have side effects.

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

If any of the following happens, stop using CYTARABINE FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body), and you may feel you are going to faint.
- infection to the whole body (sepsis), with symptoms of fever and chills, very low body temperature, urinating less than normal, rapid pulse, rapid breathing, nausea and vomiting, diarrhea, body aches.
- unexpected bleeding e.g. bleeding gums, blood in urine or vomit.
- unexpected bruises. These are the symptoms of low numbers of blood cells.
- blood in vomit or in stools (gastrointestinal necrosis or ulcer).
- severe pain in the chest and difficulty breathing (this may be a symptom of pericarditis).
- loss of vision, loss of sense of touch, mental disturbance or loss of ability to move normally, paralysis (this medicine may cause side effects to the nervous system, brain and eyes which are usually reversible but may be very serious).

These are all very serious side effects. If you have them, you may have had a serious reaction to **CYTARABINE FRESENIUS**. You may need urgent medical attention or hospitalisation.

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

- pneumonia (which can become serious and lead to organ failure).
- insufficient production or decrease in numbers of red blood cells, white blood cells or platelets, production of red blood cells larger than normal (will be determined by blood tests conducted by your doctor).

- liver damage.
- “cytarabine syndrome”, which is characterised by the following side effects that usually, occurs 6 to 12 hours after receiving **CYTARABINE FRESENIUS**. Feeling generally unwell with a high temperature, pain in bone, muscle pain and sometimes chest pain, blistery rash, swollen and sore eyes.
- abnormal bone marrow results from a biopsy, or blood results from a smear test.
- abdominal pain, chills, vomiting, fever, dark-coloured urine, diarrhoea (this may be symptoms of liver abscess, a pus-filled mass inside the liver).
- inflammation to your veins (caused by a blood clot).
- shortness of breath, sore throat, pain or difficulty swallowing.
- jaundice (seen as yellowing of the skin and whites of the eye).
- blood in your urine and impaired kidney function.
- chest pain.

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

- paralysis caused by cerebral disorder, experience problems in walking, speech problems, involuntary muscle movement caused by cerebellar disorder, tiredness, weakness, fainting.
- short or stabbing chest pain, build-up of fluid in the lungs.
- infection and inflammation of the intestines.
- prolonged state of unconsciousness (coma), fit, 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.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- inflammation or appearance of sores in the mouth, lips, or on the anus, feeling sick (nausea), being sick (vomiting), diarrhoea, abdominal pain.
- hair loss is common and may be quite severe (hair normally re-grows when your treatment course ends), skin rash, ulceration on your skin.

- feeling hot and feverish.

Frequency of side effects not known:

- you may get an infection, including infection or inflammation at the site of your injection.
- loss of appetite.
- headaches or feeling dizzy.
- sore and swollen eyes (conjunctivitis).
- slower than usual heart rate or heartbeat.
- severe pain in the abdomen, feeling sick or vomiting, inflammation or ulcers in the gullet, causing heartburn (this may be a symptom of inflammation of the pancreas).
- 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.

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

Frequent side effects:

- eye infection, irritation, pain and blurred vision.
- peeling of the skin.

Frequency of side effects not known:

- changes in your personality.
- slower than usual heart rate or heartbeat.
- stomach pain or tenderness (peritonitis), burning stomach pain (gastrointestinal ulcer).

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **CYTARABINE FRESENIUS**.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CYTARABINE FRESENIUS

Store all medicines out of reach of children.

- Hospital staff will store your medicine safely:
    - Store between 15 °C to 25 °C. Do not refrigerate or freeze.
    - After first opening, the product should be used immediately.
    - Store in the original container.
    - Keep the container in the outer carton.
    - Keep the container tightly closed.
- Do not use after the expiry date stated on the label.
- Do not use **CYTARABINE FRESENIUS** if you notice visible signs of deterioration.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CYTARABINE FRESENIUS contains

- The active substance is cytarabine.

Each 1 mL of solution contains 100 mg of cytarabine:

CYTARABINE FRESENIUS is available in four strengths:

- **CYTARABINE 100 mg/1 mL FRESENIUS:** Each 1 mL vial contains 100 mg of cytarabine.
- **CYTARABINE 500 mg/5 mL FRESENIUS:** Each 5 mL vial contains 500 mg of cytarabine.
- **CYTARABINE 1 g/10 mL FRESENIUS:** Each 10 mL vial contains 1 g of cytarabine.
- **CYTARABINE 2 g/20 mL FRESENIUS:** Each 20 mL vial contains 2 g of cytarabine.

- The other ingredients are hydrochloric acid, sodium hydroxide and water for injections. This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

What CYTARABINE FRESENIUS looks like and contents of the pack

CYTARABINE FRESENIUS is a clear, colourless solution.

CYTARABINE 100 mg/1 mL FRESENIUS:

Solution for injection is filled in 2 mL Type I, colourless glass vial closed with grey bromobutyl rubber stopper, and sealed with green aluminium flip off overseal.

CYTARABINE 500 mg/5 mL FRESENIUS:

Solution for injection is filled in 5 mL Type I, colourless glass vial closed with grey bromobutyl rubber stopper, and sealed with blue aluminium flip off overseal.

CYTARABINE 1 g/10 mL FRESENIUS:

Solution for injection is filled in 10 mL Type I, colourless glass vial closed with grey bromobutyl rubber stopper, and sealed with red aluminium flip off overseal.

CYTARABINE 2 g/20 mL FRESENIUS:

Solution for injection is filled in 20 mL Type I, colourless glass vial closed with grey bromobutyl rubber stopper, and sealed with yellow aluminium flip off overseal.

The package contains 1 vial of 1 mL, 5 mL, 10 mL and 20 mL, respectively.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

17 November 2025

Registration numbers

CYTARABINE 100 mg/1 mL FRESENIUS: 49/26/0043

CYTARABINE 500 mg/5 mL FRESENIUS: 49/26/0044

CYTARABINE 1 g/10 mL FRESENIUS: 49/26/0045

CYTARABINE 2 g/20 mL FRESENIUS: 49/26/0046

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.