

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

ZAVEDOS® 5 mg Powder for solution for injection

ZAVEDOS® 10 mg Powder for solution for injection

ZAVEDOS® RTU 5 Solution for injection

ZAVEDOS® RTU 10 Solution for injection

ZAVEDOS® RTU 20 Solution for injection

Idarubicin hydrochloride

ZAVEDOS Powder for solution for injection contains sugar.

Each ZAVEDOS 5 mg vial contains 53,7 mg lactose monohydrate.

Each ZAVEDOS 10 mg vial contains 107,4 mg lactose monohydrate

ZAVEDOS RTU Solution for injection is sugar free.

Read all of this leaflet carefully before you are given ZAVEDOS

- 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.
- ZAVEDOS 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 ZAVEDOS is and what it is used for
2. What you need to know before you are given ZAVEDOS

3. How to receive ZAVEDOS
4. Possible side effects
5. How to store ZAVEDOS
6. Contents of the pack and other information

1. What ZAVEDOS is and what it is used for

ZAVEDOS is used in the treatment of a type of leukaemia (blood cancer) in adults called acute non-lymphocytic leukaemia (ANLL), or acute myeloblastic leukaemia (AML).

ZAVEDOS is used in combination with cytarabine for first remission induction-line treatment in children previously untreated with AML.

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

ZAVEDOS should not be administered to you:

- if you are hypersensitive (allergic) to idarubicin or any other ingredients of ZAVEDOS (listed in section 6)
- if you have an allergy to other similar medicines for cancer, e.g. daunorubicin, doxorubicin, epirubicin, mitozantrone
- if you have severe liver problems, including bilirubin levels exceeding 5 mg/dL (85,5 µmol/L)
- if you have severe kidney problems
- if you have severe heart problems including heart failure, abnormal heartbeat or have had a recent heart attack
- if you have decreased bone marrow activity resulting in a reduced number of red or white blood cells or platelets
- if you have previously received the full course of treatment with the maximum dose of ZAVEDOS or other similar medicines, e.g. daunorubicin, doxorubicin, epirubicin, mitozantrone
- if you have an infection which is not under control

- if you have a history of decreased bone marrow activity caused by previous therapy or radiotherapy
- if you have been given a live attenuated vaccine and the yellow fever vaccine
- if you are pregnant, trying to become pregnant or you are breastfeeding your baby (see Pregnancy and breastfeeding)

Warnings and precautions

Special care should be taken with ZAVEDOS:

- if you are still recovering from serious side effects from a previous chemotherapy treatment
- if you have a heart disease, as ZAVEDOS can have an effect on your heart function
- if you have liver disease or kidney disease
- if you have any previous or current history of stomach problems (e.g. ulcers)
- if you have recently had a vaccination

Your doctor will monitor your heart during your therapy and will take regular blood tests to measure your levels of white and red blood cells and your platelets and the enzymes produced by your liver. This will make sure your blood, liver and kidneys are functioning properly.

ZAVEDOS may affect male fertility. Talk to your doctor about fertility preservation before starting treatment. Both men and women should use effective contraception (see “Pregnancy, breastfeeding and fertility” section).

If you desire to have children after ZAVEDOS treatment, talk to your doctor about your options.

Other medicines and ZAVEDOS

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

ZAVEDOS sometimes affects the action of other medicines and sometimes ZAVEDOS is affected by other medicines.

Make sure your doctor knows:

- if you are taking or have recently been given other medicines for cancer
- if you are taking medicines for heart problems, including calcium channel blockers, used to treat high blood pressure and angina
- if you are taking any medicines that affect the way your liver or kidneys work, e.g. some antibiotics
- if you are receiving or have received radiotherapy

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 health care provider for advice before receiving ZAVEDOS.

You should not receive ZAVEDOS if you are pregnant or breastfeeding.

Pregnancy

You must avoid becoming pregnant while you or your partner is being treated with ZAVEDOS. ZAVEDOS may harm an unborn child, so it is important to tell your doctor if you think you are pregnant or intending to father children.

Contraception in women of childbearing potential

You should always use effective birth control (contraception) whilst receiving ZAVEDOS and for at least 6,5 months after the last dose. Talk to your doctor about birth control methods that are right for you and your partner.

Contraception in men

Men should always use effective contraception whilst receiving ZAVEDOS and for at least 3,5 months after the last dose.

Breastfeeding

Do not breastfeed whilst receiving ZAVEDOS and for at least 14 days after the last dose, as some of the medicine may get into your milk and possibly harm your child.

Fertility

Both men and women should seek advice on fertility preservation before treatment.

Driving and using machines

The effect of ZAVEDOS on the ability to drive or use machinery has not been evaluated. However, before you drive or use machinery you should determine how you are affected by ZAVEDOS.

It is not always possible to predict to what extent ZAVEDOS 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 ZAVEDOS affects them.

ZAVEDOS Powder for solution for injection contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before receiving ZAVEDOS Powder for solution for injection.

3. How to receive ZAVEDOS

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

ZAVEDOS is an anticancer medicine.

You will not be expected to give yourself ZAVEDOS. The injection will be given to you by a person who is qualified to do so.

Your doctor will determine the dosage that is suitable for you.

Your doctor will tell you how long your treatment with ZAVEDOS will last.

If you have the impression that the effect of ZAVEDOS is too strong or too weak for you, tell your doctor or pharmacist.

If you receive more ZAVEDOS than you should

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the unlikely event of overdosage your doctor will manage the overdosage.

4. Possible side effects

ZAVEDOS can have side effects.

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

If any of the following happens, tell your doctor immediately:

- allergic reaction (swelling of the face, lips and tongue or other parts of the body, shortness of breath, wheezing or trouble breathing)
- skin rash, itching, redness of the skin, hives
- signs of an infection such as fever, chills, cough, hoarse throat or mouth ulcers (which may be signs of

leukopenia/low white blood cells)

- bleeding or bruising more easily than normal (signs of thrombocytopenia/low platelets)
- signs of anaemia (low red blood cells) such as tiredness, dizziness, looking pale
- shock
- signs of sepsis or blood poisoning such as high fever, chills, headache, confusion and rapid breathing
- chest pain, abnormal heartbeat, fast heartbeat
- swelling and redness along a vein which is extremely tender when touched, clotting in a vein
- vomiting blood or bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

The above list includes very serious side effects that may require urgent medical attention.

Frequent side effects:

- headache
- stomach pain or burning sensation
- nausea, vomiting, diarrhoea, loss of appetite
- loss of hair
- red coloured urine for 1 - 2 days after treatment
- fever
- abnormal liver function tests

Less frequent side effects:

- other cancers of the blood
- dehydration
- high levels of uric acid in the blood
- inflammation of the heart muscle or of the tissue surrounding the heart

- hot flushes
- mouth ulcers, redness and irritation of the throat and mouth
- skin changes including darkening of the skin and nails
- abnormal ECG (heart test)

Other side effects:

- decreased bone marrow activity
- high blood sugar
- difficulty swallowing
- tiredness

The side effects experienced by both adults and children are similar except that children are more prone to experiencing problems with their heart when receiving ZAVEDOS treatment.

If any of the side effects are troublesome, or 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. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions 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 ZAVEDOS.

5. How to store ZAVEDOS

Store all medicines out of reach of children.

ZAVEDOS would be stored at a healthcare facility.

ZAVEDOS Powder for solution for injection

Store at or below 25 °C.

Protect from light.

Reconstituted solution for injection

Should not be stored for longer than 24 hours at room temperature at or below 25 °C, or 48 hours in a refrigerator at 2 °C - 8 °C.

ZAVEDOS RTU Solution for injection

RTU solution in vial

Store in a refrigerator at 2 °C - 8 °C and protect from light.

RTU solution in 0,9 % sodium chloride infusion

ZAVEDOS RTU Solution for injection is intended for single use only and any unused portion should be discarded.

However, to avoid the risk of microbial contamination, it is recommended that the solution be used as soon as possible after adding it to the 0,9 % sodium chloride infusion bag.

Any remaining injection will be disposed of correctly by the nurse or doctor at the hospital.

6. Contents of the pack and other information

What ZAVEDOS contains

- The active substance is idarubicin hydrochloride.
- The other ingredients in ZAVEDOS Powder for solution for injection are lactose monohydrate, water for injection and nitrogen.

- The other ingredients in ZAVEDOS RTU Solution for injection are glycerol and water for injection.
Hydrochloric acid may be present for pH adjustment.

What ZAVEDOS looks like and contents of the pack

ZAVEDOS Powder for solution for injection

Porous red-orange, freeze-dried cake or mass in a clear glass vial.

Vials containing 5 mg and 10 mg idarubicin hydrochloride.

ZAVEDOS RTU Solution for injection

Plastic vials containing a red-orange, clear mobile solution.

One single-use vial containing 5 mg, 10 mg and 20 mg idarubicin hydrochloride. Each polypropylene vial is closed with a rubber stopper and an aluminium overseal with a purple plastic flip-off top. The vial is packed into an outer cardboard carton.

Holder of Certificate of Registration

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