

ZAVEDOS INJECTION

Idarubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this carefully before being treated with ZAVEDOS.

It does not contain all the available information.

If you have any questions, or are unsure about anything, ask your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with ZAVEDOS against the expected benefits it will have for you.

Ask your doctor if you have any concerns about being treated with this medicine.

Keep this leaflet even after your treatment with ZAVEDOS is finished.

You may need to read it again.

What ZAVEDOS is used for

ZAVEDOS is used in the treatment of adult leukaemia known as AML (acute myelogenous leukaemia). It works by stopping cancer cells from growing and multiplying.

ZAVEDOS may be used alone or in combination with other chemotherapy.

Ask your doctor if you have any questions about why ZAVEDOS has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before being treated with ZAVEDOS

When you must not use it

Do not take ZAVEDOS if you have an allergy to:

- idarubicin hydrochloride
- other similar medicines for cancer (daunorubicin, doxorubicin, epirubicin and mitozantrone)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take ZAVEDOS if you have:

- severe kidney problems
- severe liver problems
- severe heart problems, including abnormal heart beat or a recent heart attack.
- a severe infection, with signs such as fever, severe chills, sore throat or mouth ulcers
- reduced number of red or white blood cells or platelets
- previously received the full course of treatment with the maximum dose of idarubicin or other similar medicines, e.g. daunorubicin, doxorubicin, epirubicin, mitozantrone.

Do not take ZAVEDOS if you are pregnant or intend to become pregnant.

Do not take ZAVEDOS if your partner is trying to become pregnant.

ZAVEDOS may cause birth defects if either you or your partner are taking it.

Do not take ZAVEDOS if you are breastfeeding or intend to breastfeed.

It is not known whether ZAVEDOS can pass into the breast milk and affect the child. If you have any concerns about breast feeding, consult your doctor.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have:

- kidney disease
- liver disease
- heart disease
- had previous treatment with ZAVEDOS or other chemotherapy
- had previous radiation therapy
- anaemia
- had a bone marrow transplant
- bone marrow depression, a blood disorder with low platelet, red blood and white blood cell counts
- infection or high temperature, severe chills, sore throat or mouth ulcers
- stomach ulcers, or vomiting blood or bleeding from the back passage.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ZAVEDOS may interfere with each other. These include:

- other medicines for cancer
- some medicines for heart problems, including calcium channel blockers, used to treat high blood pressure and angina.
- certain medicines that may affect your liver and kidney function, e.g. some antibiotics and antifungals
- vaccines.

These medicines may increase some side effects of ZAVEDOS, including the effects on the heart, blood cells, the stomach or bowels, and reduce the body's ability to fight infection.

If you are concerned about taking any other medications whilst having ZAVEDOS treatment, ask your doctor or pharmacist.

They have more information on medicines to be careful with or avoid while taking ZAVEDOS.

How ZAVEDOS is given

ZAVEDOS injection will be prepared in a hospital and given to you by a doctor or nurse.

ZAVEDOS is given as a slow intravenous injection, usually on 3 consecutive days. If other cancer medicines are to be given in combination with ZAVEDOS, further days of treatment may be involved. This is called an induction course.

Another course of treatment may be needed depending on your response to treatment. Additional treatment will not be repeated until your blood returns to acceptable levels and any unwanted effects have been controlled.

Inform your doctor or nurse immediately if pain, redness or swelling develops at the injection site.

If you are given too much (overdose)

Overdose may result in nausea, vomiting and bleeding from the stomach.

Very high doses of ZAVEDOS may cause severe damage to the heart within 24 hours and may seriously affect the production of new red and white blood cells within 1 or 2 weeks.

While being treated with ZAVEDOS

Things you must do

Keep all appointments with your doctor so that your progress can be checked.

ZAVEDOS lowers the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

Medicines such as ZAVEDOS are also known to affect the heart particularly at high doses and after a long period of treatment.

Regular tests to monitor your blood count, kidney and liver function, and your heart will be required before, during and after treatment.

Tell your doctor immediately if you or your partner becomes pregnant while you are taking or just after you stop taking ZAVEDOS.

This medicine may cause birth defects if either you or your partner are taking it.

Use a proven method of birth control such as the contraceptive pill or a condom while taking the medicine and for at least 12 weeks after stopping treatment.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are being treated with ZAVEDOS.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are using this medicine.

If any time before, during or after treatment with ZAVEDOS you experience any difficulties, consult your doctor.

Things to be careful of

Special care should be taken if it is necessary that you drive or operate machinery while undergoing treatment with ZAVEDOS, especially if you are in a weakened condition.

Take the following precautions to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate
- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work

- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters
- Avoid contact sports or other situations where you may bruise or get injured.

Side effects

Tell your doctor as soon as possible if you do not feel well during or after treatment with ZAVEDOS.

All medicines can have side effects. This medicine may have unwanted side effects in a few people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Most of the side effects listed below are reversible.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- red coloured urine for 1 - 2 days after treatment (this is normal and is no cause for alarm)
- nausea, vomiting, diarrhoea, loss of appetite
- stomach pain and discomfort
- mouth ulcers, redness and irritation of the throat and mouth with difficulty on swallowing and eating
- skin changes such as darker areas of the skin and nails
- loss of hair
- hot flushes.

The above list includes the milder side effects of your medicine.

If any of the following happen, 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 infection such as fever, chills, cough, hoarse throat or mouth ulcers
- bleeding or bruising more easily than normal
- signs of anaemia such as headaches, shortness of breath when exercising, dizziness, looking pale
- shock due to a dangerous drop in blood pressure, which, may lead to collapse and coma - signs include rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting
- signs of sepsis or blood poisoning such as high fever, chills, headache, confusion and rapid breathing
- chest pain, abnormal heartbeat, fast heartbeat
- shortness of breath, swelling in the feet or legs due to fluid build-up
- 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, an increase in liver enzyme levels, high blood levels of uric acid) can only be found when your doctor does tests from time to time to check your progress.

After treatment with ZAVEDOS

Storage

ZAVEDOS solution for injection is normally stored in a hospital.

ZAVEDOS solution for injection is stored in the refrigerator between 2 to 8°C. (Refrigerate. Do not freeze.) Protect from light.

Disposal

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

Product description

What it looks like

ZAVEDOS injection is an orange-red coloured solution contained in a plastic vial.

It is available in two different sizes: 5 mg/5 mL and 10 mg/10 mL.

Ingredients

The active ingredient in ZAVEDOS is idarubicin hydrochloride.

ZAVEDOS injection also contains glycerol, hydrochloric acid and water as inactive ingredients.

Supplier

Pfizer Australia Pty Ltd
 ABN 50 008 422 348
 38-42 Wharf Road
 West Ryde NSW 2114

Toll free number 1800 675 229

Australian Registration numbers:

5 mg/5 mL vial: AUST R 67397

10 mg/10 mL vial: AUST R 67398

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