

ZAVEDOS®

Idarubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before treatment with ZAVEDOS.

This leaflet answers some common questions about this medicine.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ZAVEDOS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Please keep this leaflet.

You may need to read it again.

What ZAVEDOS is used for

ZAVEDOS is used to treat a type of leukaemia in adults 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.

ZAVEDOS is only available with a doctor's prescription.

It is not addictive.

Before treatment with ZAVEDOS

When ZAVEDOS must not be used

Do not take ZAVEDOS if you have an allergy to:

- any medicine containing idarubicin hydrochloride
- other similar medicines for cancer, e.g., daunorubicin, doxorubicin, epirubicin, mitoxantrone
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to ZAVEDOS 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 the medicine if you have:

- severe kidney problems
- severe liver problems
- severe heart problems including heart failure, abnormal heartbeat 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/mitoxantrone.

Do not take the medicine if you are pregnant or trying to become pregnant.

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

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

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

Women should not breastfeed during treatment with Zavedos and for at least 14 days after the last dose. Consult your doctor or midwife if you have any concerns about being unable to breastfeed for this period.

Do not take ZAVEDOS after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before treatment with ZAVEDOS

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 any 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.

Talk to your doctor about an effective contraceptive method and fertility preservation before starting your treatment.

Women of childbearing potential should use effective contraception during treatment with ZAVEDOS and for at least 6.5 months after the final dose. Men with female partners of childbearing potential must use an effective contraception during treatment and for at least 3.5 months after the final dose. If planning for conception, it is advisable to seek genetic counselling.

Taking other medicines

Tell your doctor if you are taking any other medicines, including those you buy without a prescription from a pharmacy, supermarket or health food store.

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.

Treatment with ZAVEDOS

ZAVEDOS

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

It 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 take or are given too much (overdose)

Overdose may result in nausea, vomiting, 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.

Overdose is unlikely, as ZAVEDOS is given in hospital under the supervision of a doctor.

If you think you may have been given too much ZAVEDOS, immediately telephone your doctor or the Poisons Information Centre (telephone 131 126) or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have been treated with too much ZAVEDOS. Do this even if there are no signs of discomfort or poisoning.

You will need urgent medical attention.

While you are 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.

The medicine may cause birth defects if you or your partner is taking it.

You and your partner should use a proven method of birth control, such as the contraceptive pill or a condom during treatment with ZAVEDOS.

Women of childbearing potential should use an effective contraception during treatment and continue using an effective

contraception for at least 6.5 months after stopping treatment. Men with female partners of childbearing potential must use an effective contraception during treatment and for at least 3.5 months after the final dose.

Tell any other doctors, dentists or pharmacists who treat you that you are being treated with ZAVEDOS.

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.

Things you must not do

Do not stop taking ZAVEDOS, or change the dose, unless your doctor tells you to.

Do not start to take any other medicine before talking to your doctor or pharmacist.

Do not use this medicine to treat any other conditions unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not breastfeed during treatment for at least 14 days after last dose.

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:

- red coloured urine for 1-2 days after treatment (this is normal and is no cause for alarm)
- nausea and vomiting, diarrhoea, loss of appetite
- stomach pain and discomfort
- mouth ulcers, redness and irritation of the throat and mouth with difficulty in 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.

Tell your doctor immediately if you notice any of the following:

- 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 or hives
- signs of infection such as fever, chills, cough or mouth ulcers
- signs of anaemia such as headaches, shortness of breath when exercising, dizziness, looking pale
- bleeding or bruising more easily than normal
- 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, rapid breathing
- chest pain, abnormal heartbeat, fast heartbeat
- shortness of breath, swelling in the feet or legs due to fluid build-up
- vomiting blood or bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- swelling and redness along a vein which is extremely tender when touched, clotting in a vein if you are being treated with ZAVEDOS Solution for Injection.

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

Tell your doctor if you notice anything else 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 using ZAVEDOS

Storage

Solution for Injection

ZAVEDOS Solution for Injection is normally stored in a hospital.

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

Disposal

Any remaining ZAVEDOS Solution for Injection will be disposed by the nurse or doctor at the hospital.

Product description

What it looks like

ZAVEDOS Solution for Injection is available in two different sizes: 5 mg/5 mL and 10 mg/10 mL It is a red-orange coloured solution contained in a plastic vial.

Ingredients

ZAVEDOS Solution for Injection contain idarubicin hydrochloride as the active ingredient.

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

Supplier

Pfizer Australia Pty Ltd

SYDNEY, NSW.

Toll free number: 1800 675 229.

Australian Registration numbers

5 mg/5 mL Solution for Injection, AUST R 67397.

10 mg/10 mL Solution for Injection, AUST R 67398.

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