

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given ZAVEDOS?

ZAVEDOS contains the active ingredient idarubicin hydrochloride. ZAVEDOS is used to treat a type of leukemia in adults known as AML (acute myelogenous leukaemia).

For more information, see Section [1. Why am I being given ZAVEDOS?](#) in the full CMI.

2. What should I know before I am given ZAVEDOS?

You will not be given ZAVEDOS if you have ever had an allergic reaction to idarubicin hydrochloride, other similar medicines for cancer or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions especially problems with your heart, take any other medicines, or are pregnant or unsure if you are pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given ZAVEDOS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZAVEDOS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is ZAVEDOS given?

ZAVEDOS is injected slowly into a vein. It must only be given by a doctor or nurse. Your doctor will decide what dose, how often, and how long you will receive it.

More instructions can be found in Section [4. How is ZAVEDOS given?](#) in the full CMI.

5. What should I know while being given ZAVEDOS?

Things you should do	- Remind any doctor, dentist, nurse or pharmacist you visit that you are being given ZAVEDOS. - Tell your doctor immediately if you or your partner becomes pregnant while you are taking or just after you stop taking ZAVEDOS. - You and your partner should use a proven method of birth control during treatment with ZAVEDOS. Proven birth control must continue to be used for at least 6 and a half months after the last dose for women and 3 and a half months after the last dose for men.
Things you should not do	- You should not be given this medicine if you are pregnant or you or your partner are planning to become pregnant. - Do not breastfeed during treatment with ZAVEDOS and for at least 14 days after last dose.
Driving or using machines	Be careful driving or operating machinery until you know how this medicine affects you. If you are feeling dizzy or drowsy do not drive, operate machinery, or do anything else that could be dangerous.

For more information, see Section [5. What should I know while being given ZAVEDOS?](#) in the full CMI.

6. Are there any side effects?

Side effects may include: red-coloured urine for 1-2 days after treatment, nausea, vomiting, diarrhoea, loss of appetite, stomach pain & discomfort, mouth ulcers, redness & irritation of the throat & mouth with difficulty in swallowing & eating, skin changes, loss of hair, hot flushes, allergic reactions; skin rash; itching; redness of the skin or hives; signs of infection; signs of anaemia, bleeding or bruising more easily than normal; shock due to a dangerous drop in blood pressure which may lead to collapse & coma; signs of sepsis or blood poisoning; 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 or bloody diarrhoea; swelling and redness along a vein which is extremely tender when touched.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZAVEDOS®

Active ingredient: idarubicin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZAVEDOS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZAVEDOS.**

Where to find information in this leaflet:

1. [Why am I being given ZAVEDOS?](#)
2. [What should I know before I am given ZAVEDOS?](#)
3. [What if I am taking other medicines?](#)
4. [How is ZAVEDOS given?](#)
5. [What should I know while being given ZAVEDOS?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given ZAVEDOS?

ZAVEDOS contains the active ingredient idarubicin hydrochloride.

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

Your doctor may have prescribed ZAVEDOS for another reason.

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

There is no evidence that ZAVEDOS is addictive.

ZAVEDOS is only available with a doctor's prescription.

2. What should I know before I am given ZAVEDOS?

Warnings

You should not be given ZAVEDOS if:

- you are allergic to idarubicin hydrochloride, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any other similar medicines for cancer, e.g., daunorubicin, doxorubicin, epirubicin, mitoxantrone
- Some of the symptoms of an allergic reaction may include:
 - o shortness of breath, wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.
- you have severe kidney problems
- you have severe liver problems

- you have severe heart problems including heart failure, abnormal heartbeat or a recent heart attack
- you have a severe infection, with signs such as fever, severe chills, sore throat or mouth ulcers
- you have a reduced number of red or white blood cells or platelets
- you have previously received the full course of treatment with the maximum dose of idarubicin or other similar medicines e.g., daunorubicin, doxorubicin, epirubicin, mitoxantrone/mitoxantrone
- you are pregnant or trying to become pregnant.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney disease
- liver disease
- heart disease
- previous treatment with ZAVEDOS or any other chemotherapy
- previous radiation therapy
- anaemia
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

You should not be given ZAVEDOS if you are pregnant or intend to become pregnant or your partner is trying to become pregnant.

This medicine may cause birth defects if you or your partner is being treated with it.

Talk to your doctor 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.

Contraception

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

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with ZAVEDOS and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZAVEDOS.

4. How is ZAVEDOS given?

How much and how long is it given

ZAVEDOS is given in a clinical setting by a nurse or doctor. 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 weight.

How ZAVEDOS is given

ZAVEDOS is injected slowly into a vein.

If too much ZAVEDOS is given

Since ZAVEDOS is given in a hospital or clinic under the supervision of a doctor, it is very unlikely that you will be given too much of the medicine. Your doctor or nurse will be monitoring your progress and checking the medicine that you are given.

If you think that you may have been given too much ZAVEDOS, you may need urgent medical attention.

Symptoms of an overdose may include the side effects listed in Section [6. Are there any side effects?](#) but are usually of a more severe nature

5. What should I know while being given ZAVEDOS?

Things you should do

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

You will have regular tests to monitor your blood count, kidney and liver function, and your heart before, during and after treatment.

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

Call your doctor straight away if you:

- or your partner becomes pregnant while you are taking or just after you stop taking ZAVEDOS
- develop redness or swelling at the injection site.

Things to be careful of

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZAVEDOS affects you.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Renal disorders • red coloured urine for 1-2 days after treatment (this is normal and is no cause for alarm). Gastrointestinal disorders • nausea and vomiting • diarrhoea • loss of appetite • stomach pain and discomfort	Speak to your doctor if you have any of these side effects and they worry you.

Side effects	What to do
Skin and subcutaneous tissue disorders • mouth ulcers • skin changes such as darker areas of the skin and nails • loss of hair Vascular disorders • hot flushes	

More serious side effects

More serious side effects	What to do
Cardiac disorders • chest pain • abnormal heartbeat • fast heartbeat • shock due to 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. Skin and subcutaneous tissue disorders • allergic reactions (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 • bleeding or bruising more easily than normal • swelling and redness along a vein which is extremely tender when touched • clotting in a vein • swelling in the feet or legs due to fluid build-up. General disorders and administrative site conditions • signs of infection such as fever, chills, cough or mouth ulcers • signs of sepsis or blood poisoning such as high fever, chills, headache, confusion, rapid breathing Blood and lymphatic system disorders	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects.

More serious side effects	What to do
• signs of anaemia such as headaches, shortness of breath, when exercising, dizziness, looking pale Gastrointestinal disorders • vomiting blood • bleeding from the back passage • black sticky bowel motions (stools) • bloody diarrhoea	

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

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZAVEDOS contains

Active ingredient (main ingredient)	idarubicin hydrochloride
Other ingredients (inactive ingredients)	glycerol hydrochloric acid water

Do not take this medicine if you are allergic to any of these ingredients.

ZAVEDOS does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What ZAVEDOS looks like

ZAVEDOS is a red-orange coloured solution contained in a plastic or a glass vial.

Australian Registration Numbers

ZAVEDOS idarubicin hydrochloride 5mg/5mL injection vial - ARTG R 67397

ZAVEDOS idarubicin hydrochloride 10mg/10mL injection vial - ARTG R 67398

Who distributes ZAVEDOS

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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