

## 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.



This medicine is new. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I receiving Vyxeos?

Vyxeos contains the active ingredients, daunorubicin hydrochloride and cytarabine. It is used to treat adults with newly diagnosed acute myeloid leukaemia (a cancer of the white blood cells), when the leukaemia was caused by previous treatments (known as therapy related acute myeloid leukaemia) or when there are certain changes in the bone marrow (known as acute myeloid leukaemia with “myelodysplasia-related changes”).

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

### 2. What should I know before I receive Vyxeos?

Do not use if you have ever had an allergic reaction to Vyxeos or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. You should avoid becoming pregnant while receiving Vyxeos as it may harm your baby. You should not breastfeed during Vyxeos therapy.**

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

### 3. What if I am taking other medicines?

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

### 4. How will I be given Vyxeos?

Vyxeos therapy can only be initiated by a doctor with experience in using medicines to treat cancers. Vyxeos will be given to you as drip infusion into your vein over one and half hours (90 minutes). Your doctor will calculate the dose you need.

Further details can be found in Section [4. How will I be given Vyxeos?](#) in the full CMI.

### 5. What should I know while receiving Vyxeos?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you become or intend to become pregnant; or are breastfeeding or intend to breastfeed.</li><li>• Remind any doctor, dentist, or pharmacist you visit that you are being treated with Vyxeos. Tell your doctor you are being treated with Vyxeos if you are about to start on a new medicine.</li><li>• Keep your appointments with your doctor and any tests to monitor your progress and check for any side effects.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Vyxeos affects you. Vyxeos may cause tiredness, sleepiness, or dizziness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Your doctor or pharmacist has more information on how to store Vyxeos.</li></ul>

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

### 6. Are there any side effects?

Side effects include rash, nausea, vomiting, diarrhoea, stomach or gut pain, tiredness, muscle, joint or bone pain, and headache. Serious side effects include allergic reactions, bleeding or bruising, chest pain, swelling in the legs, fever, and infection. 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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Vyxeos®

Active ingredients: *daunorubicin hydrochloride / cytarabine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about Vyxeos.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about Vyxeos.**

**Where to find information in this leaflet:**

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

### 1. Why am I receiving Vyxeos?

**Vyxeos contains the active ingredients daunorubicin hydrochloride and cytarabine.** Vyxeos is a combination of antineoplastic medicines, which are used to kill cancer cells by stopping them from growing and dividing.

**Vyxeos is used to treat adults with newly diagnosed acute myeloid leukaemia (a cancer of the white blood cells), when the leukaemia was caused by previous treatments (known as therapy related acute myeloid leukaemia) or when there are certain changes in the bone marrow (known as acute myeloid leukaemia with “myelodysplasia-related changes”).**

### 2. What should I know before I receive Vyxeos?

#### Warnings

**Do not receive Vyxeos if:**

- you are allergic to daunorubicin or cytarabine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have or ever have had any other medical conditions including the following:
  - problems with your heart including heart disease and heart attack.
  - problems with your liver or kidneys
  - problems with how you use copper or remove it from the body, such as Wilson's disease.

- have taken doxorubicin, idarubicin, mitozantrone, epirubicin or any other anthracycline cancer medicines.
- take any medicines for any other conditions.

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

Check with your doctor if you are pregnant or intend to become pregnant. You should avoid becoming pregnant while receiving Vyxeos as it may harm your baby. You must use an effective method of contraception during treatment and for 6 months after the last dose of Vyxeos.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not breastfeed during Vyxeos therapy.

#### Males

Men and their sexual partners who can bear children, should use effective contraception during treatment and for 6 months after the last dose of Vyxeos.

### 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.

**Medicines that may increase the risk of side effects include:**

- medicines that could affect your heart, such as doxorubicin, idarubicin, mitozantrone, epirubicin or any other anthracycline cancer medicines.
- medicines that could affect your liver.

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

### 4. How will I be given Vyxeos?

Vyxeos therapy can only be initiated by a doctor with experience in using medicines to treat cancers.

Vyxeos will be given to you as drip infusion into your vein over one and half hours (90 minutes).

Your doctor may ask you to take medicines for nausea, vomiting, or other possible side effects of treatment before or during treatment with Vyxeos.

## How much to receive?

Your doctor will calculate the dose you need. The dose will depend upon factors such as, your height, weight, or age.

Your doctor may adjust your dose or discontinue treatment if you experience any side effects.

## When to take Vyxeos

Vyxeos will be given to you according to a treatment schedule. There may be some weeks apart between treatments. To begin with you will be given a drip infusion every second day for 5 days. Your doctor will then assess your progress and any side effects and decide if you need any further treatment.

## If you forget to receive Vyxeos

Let your doctor know as soon as possible if you miss a dose of Vyxeos.

## If you receive too much Vyxeos

If you think that you have received too much Vyxeos, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while receiving Vyxeos?

### Things you should do

- Keep your appointments with your doctor and any tests to monitor your progress and check for any side effects.
- If you are about to be started on a new medicine, tell your doctor you are being treated with Vyxeos.

### Call your doctor straight away if you:

- become or intend to become pregnant.
- are breastfeeding or intend to breastfeed.

Remind any doctor, dentist, or pharmacist you visit that you are being treated with Vyxeos.

### Driving or using machines

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

Vyxeos may cause tiredness, sleepiness, or dizziness in some people.

### Looking after your medicine

- It is unlikely that you will be asked to store Vyxeos yourself. It will usually be stored in the pharmacy or on the ward.

- Keep the vial in the outer carton to protect the contents from light.
- Store the vial in a refrigerator between 2°C and 8°C in an upright position.

## When to discard your medicine

Your doctor or pharmacist will know when to discard your medicine. The reconstituted solution can be stored in a refrigerator between 2°C and 8°C for up to 4 hours while upright.

The infusion solution can be stored in a refrigerator between 2°C and 8°C for up to 4 hours. However, the total storage time for the reconstituted solution and infusion solution should not be more than 4 hours.

## Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

## 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Stomach or gut-related:</b></p> <ul style="list-style-type: none"><li>• Nausea or vomiting</li><li>• Diarrhoea or constipation</li><li>• Gut or stomach pain</li><li>• Indigestion</li><li>• Decreased appetite</li></ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"><li>• Rash</li><li>• Numbness in the hands and feet</li><li>• Itching</li><li>• Excessive sweating</li></ul> <p><b>Nervous or mental health-related:</b></p> <ul style="list-style-type: none"><li>• Headache</li><li>• Problems sleeping</li><li>• Anxiety</li><li>• Confusion</li></ul> <p><b>Muscle or bone-related:</b></p> <ul style="list-style-type: none"><li>• Pain or aches in the muscle, joints or bone</li></ul> <p><b>Other:</b></p> <ul style="list-style-type: none"><li>• Problems with eyesight</li><li>• Cough</li><li>• Tiredness or lack of energy</li><li>• Hair loss</li><li>• High or low blood pressure</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Infection-related:</b></p> <ul style="list-style-type: none"><li>Fever, chills, sore throat, cough, mouth ulcers</li></ul> <p><b>Bleeding-related:</b></p> <ul style="list-style-type: none"><li>Bleeding or bruising</li><li>Bleeding nose</li><li>Red, brown, or purple spots on the skin</li></ul> <p><b>Heart or lung-related:</b></p> <ul style="list-style-type: none"><li>Chest pain</li><li>Slow, fast, or irregular heartbeat</li><li>Shortness of breath, cough, dizziness, swelling in the legs, excessively tired or weak</li></ul> <p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"><li>Swelling of the face, lips, tongue, or throat which may cause difficulty in breathing or swallowing</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**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](http://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 or receiving any of your medicines.**

## 7. Product details

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

### What Vyxeos contains

<b>Active ingredients (main ingredients)</b>	Each vial contains 44 mg of daunorubicin as daunorubicin hydrochloride and 100 mg of cytarabine
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>distearoylphosphatidylcholine</li><li>distearoylphosphatidylglycerol</li><li>cholesterol</li><li>copper gluconate</li><li>trolamine</li><li>sucrose</li></ul>

<b>Potential allergens</b>	<ul style="list-style-type: none"><li>daunorubicin</li><li>cytarabine</li></ul>
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**Do not take this medicine if you are allergic to any of these ingredients.**

### What Vyxeos looks like

Vyxeos is a purple powder or cake. Your doctor or nurse will make up a solution of the powder in sterile water. The solution will then be used to make a drip infusion solution.

Vyxeos comes in a 50 mL glass vial with rubber stopper and aluminium overseal. (AUST R 363250)

### Who distributes Vyxeos?

Jazz Pharmaceuticals ANZ Pty Ltd

One International Towers Sydney,

Watermans Quay, Barangaroo NSW 2000,

Australia

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