

PFIZER DAUNORUBICIN

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 using PFIZER DAUNORUBICIN?

PFIZER DAUNORUBICIN powder for injection contains the active ingredient daunorubicin hydrochloride. PFIZER DAUNORUBICIN is used to treat different types of cancers including leukaemia (a type of cancer that affects the blood and bone marrow or a type of blood cancer where excess of immature white blood cells is made by the bone marrow); cancer in certain nerve cells or cancer affecting muscle cells.

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

2. What should I know before I use PFIZER DAUNORUBICIN?

Do not use if you have ever had an allergic reaction to PFIZER DAUNORUBICIN powder for injection or any of the ingredients listed at the end of the CMI.

Do not use if you have a severe reduction in blood cell count, severe heart disease, a severe infection or severe liver or kidney disease.

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.

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

3. What if I am taking other medicines?

Some medicines may interfere with PFIZER DAUNORUBICIN 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 PFIZER DAUNORUBICIN given?

PFIZER DAUNORUBICIN 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 PFIZER DAUNORUBICIN given?](#) in the full CMI.

5. What should I know while using PFIZER DAUNORUBICIN?

Things you should do

- Remind any doctor or dentist you visit that you are being given PFIZER DAUNORUBICIN powder for injection.
- Tell your doctor immediately if you become pregnant while being treated with PFIZER DAUNORUBICIN. If you have the potential to fall pregnant, you must use effective contraception during treatment. If you are male and your partner has the potential to fall pregnant, you must use effective contraception during your treatment.
- Tell your doctor if you experience any signs of infection, such as sinusitis, tooth abscess,

	sore red mouth, fever, sore throat, unusual bleeding or bruising, swollen joints, nausea, vomiting, especially if it lasts for 24 to 48 hours.
Things you should not do	<ul style="list-style-type: none"> • Do not use this medicine if you are pregnant or you or your partner are planning to become pregnant. • Do not breastfeed during treatment with PFIZER DAUNORUBICIN.

For more information, see Section [5. What should I know while using PFIZER DAUNORUBICIN](#) in the full CMI.

6. Are there any side effects?

Common side effects of this medicine may include: infection, heart problems, difficulty in breathing, blueish skin, swelling of the feet, legs or stomach, unusual bruising or bleeding, nausea, vomiting, diarrhoea or abdominal pain, sore throat or mouth ulcers, sores in mouth and on lips, hair loss, redness of the skin, rash, fever, pain, redness or pain where the injection is being given.

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.

PFIZER DAUNORUBICIN

Active ingredient(s): *daunorubicin hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using **PFIZER DAUNORUBICIN**. 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 **PFIZER DAUNORUBICIN**.

Where to find information in this leaflet:

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

1. Why am I using PFIZER DAUNORUBICIN?

PFIZER DAUNORUBICIN contains the active ingredient daunorubicin hydrochloride and belongs to a group of anticancer medicines known as cytotoxic anthracycline antibiotics.

Daunorubicin hydrochloride works by preventing the growth of cancer cells and eventually destroying them. It is used to treat different types of cancers including the following types of cancers leukaemia, a type of cancer that affects the blood and bone marrow (the organ that produces blood cells) or a type of blood cancer where excess of immature white blood cells is made by the bone marrow); cancer in the small glands on top of the kidneys (adrenal glands) or cancer affecting muscle cells.

2. What should I know before I use PFIZER DAUNORUBICIN?

Warnings

Do not use PFIZER DAUNORUBICIN if:

- you are allergic to medicines from the same group (anthracyclines or anthracenediones)
- you have an allergy to daunorubicin or any of the ingredients listed at the end of this leaflet

- you have heart disease or heart problems, have recently had a heart attack or experienced chest pain or have a severe form of irregular heartbeats (arrhythmia)
- you have a severe infection
- you have severe liver or renal function impairment
- you have long-term, reduced bone marrow function (reduced blood cell production)
- you have a low blood count following chemotherapy or radiotherapy
- if you have previously received the total permissible dose of Daunorubicin or another medicine from the anthracycline group
- if you are pregnant

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

Do not use this medicine if you or your partner are pregnant or planning to become pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

It is not known whether daunorubicin passes into breast milk. Therefore, breastfeeding is not recommended during treatment with daunorubicin.

Contraception

Women of childbearing potential should use effective contraception during treatment with daunorubicin and for at least 27 weeks after the final dose. Male patients being treated with daunorubicin must use effective contraception during treatment and for at least 14 weeks after the final dose if your partner is of childbearing potential. You should seek advice on fertility preservation before treatment.

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 and daunorubicin may interfere with each other. These include:

- other anticancer drugs
- medicines used to treat gout, such as allopurinol, colchicine, probenecid, sulphinpyrazone
- other medicines that affect bone marrow function
- drugs which may cause liver problems
- some vaccines (injections to prevent you getting a certain disease)

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

4. How is PFIZER DAUNORUBICIN given?

How much and how long is it given

PFIZER DAUNORUBICIN 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 and height, age, blood tests, how well your liver is working and whether or not other medicines are being given at the same time.

If too much PFIZER DAUNORUBICIN is given

Since PFIZER DAUNORUBICIN 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 have been given too much PFIZER DAUNORUBICIN 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 PFIZER DAUNORUBICIN?

Things you should do

Keep all your doctor's appointments.

You will need regular follow-up to check you progress.

You will also have blood tests and heart monitoring to check for side effects.

Tell your doctor immediately if you become pregnant while being treated with PFIZER DAUNORUBICIN.

Call your doctor straight away if you experience any of the following during or after treatment:

- any signs of infection, such as sinusitis, tooth abscess, sore red mouth, fever, sore throat

Treatment with daunorubicin can cause bone marrow damage, which can result in infections and/or severe bleeding. Your doctor will closely monitor your blood cell levels to be able to respond quickly and start treatment if these conditions occur.

- unusual bleeding or bruising
- gout, a disease with painful, swollen joints

- nausea, vomiting, especially if it lasts for 24 to 48 hours.

Tell your doctor if you are having or have had radiotherapy.

Tell your doctor if you are having or have had treatment with other anticancer medicines.

Tell your doctor if you have liver problems or kidney problems.

You should not be given this medicine if you have severe liver or kidney problems. Your doctor may need to monitor your liver or kidney function and adjust the daunorubicin dose if necessary.

Tell your doctor if you have or have had heart disease or have high blood pressure.

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

Driving or using machines

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

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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	What to do
<ul style="list-style-type: none">• flushing of the face (hot and red)• nausea, vomiting, diarrhoea, abdominal pain• dark areas on the nails and skin• hair loss on all parts of the body• redness of the skin• reddish urine• dehydration	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects	What to do
<ul style="list-style-type: none">• infections, fever, severe chills, sore throat, mouth ulcers	Call your doctor straight away, or go straight to the Emergency Department at your

Serious side effects	What to do
<ul style="list-style-type: none"> ● severe nausea, vomiting or diarrhoea lasting more than 24 hours ● sores in mouth and on lips, heartburn, or difficulty swallowing ● unusual bruising or bleeding ● heart problems ● difficulty in breathing or any swelling ● burning, stinging, hotness, redness or pain where the injection is being given ● abdominal pain ● swelling, redness or tenderness in the vein ● itchy rash or skin reaction 	<p>nearest hospital if you notice any of these serious side effects.</p>

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

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 PFIZER DAUNORUBICIN contains

Active ingredient (main ingredient)	Daunorubicin hydrochloride
Other ingredients (inactive ingredients)	Mannitol

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

What PFIZER DAUNORUBICIN looks like

PFIZER DAUNORUBICIN is a red-orange powder in a clear glass vial

Australian Registration Numbers

20 mg per vial - AUST R 399600

Who distributes PFIZER DAUNORUBICIN

Pfizer Australia Pty Ltd

SYDNEY, NSW.

Toll Free Number: 1800 675 229.

www.pfizermedinfo.com.au

This leaflet was prepared in September 2023