

Pfizer (Perth) Daunorubicin

Daunorubicin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Daunorubicin.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you using Daunorubicin against the benefits it is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital.

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

Keep this leaflet.

You may need to read it again.

What Daunorubicin is used for

Daunorubicin belongs to a group of anticancer medicines known as cytotoxic anthracycline antibiotics. Daunorubicin 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)
- cancer affecting muscle cells.

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

Your doctor may have prescribed it for another purpose.

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

Before you are given Daunorubicin

When you must not be given it

You should not be given Daunorubicin if you:

- are allergic to medicines from the same group (anthracyclines or anthracenediones)
- have an allergy to Daunorubicin or any of the ingredients listed at the end of this leaflet
- 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)
- have severe infections
- have severe liver or renal function impairment
- have long-term, reduced bone marrow function (blood cell production)

- 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.

Tell your doctor if you have been given Daunorubicin or doxorubicin previously.

Your doctor will determine if you should continue to be treated with Daunorubicin.

Daunorubicin or other anthracyclines may increase the risk of heart damage. The total dose (cumulative dose) is 500-600 mg/m² for adults, 300 mg/m² for children over two years old and 10 mg/kg body weight for children under two years old.

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

It may affect the developing baby if you or your partner are being treated with Daunorubicin during pregnancy.

If you are not sure whether you should be given Daunorubicin, talk to your doctor.

Before you are given it

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

Tell your doctor if you or your partner are pregnant or planning to become pregnant.

Men and women of childbearing potential should use effective contraception during treatment with daunorubicin and for at least

27 weeks after the final dose. If your male partner is being treated with daunorubicin, women of childbearing potential should use an effective contraception during his treatment and for at least 14 weeks after the final dose.

You should seek advice on fertility preservation before treatment.

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.

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.

The elderly, children and infants are at greatest risk of heart failure when being treated with Daunorubicin. The doctor will carefully monitor your heart function before, during and after treatment in order to detect signs of damage as early as possible and to start appropriate treatment in a timely manner.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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, sulphapyrazone
- other medicines that affect bone marrow function
- drugs which may cause liver problems
- some vaccines (injections to prevent you getting a certain disease)

You may need different amounts of your medicines or you may need to take different medicines. Your doctor will advise you.

How Daunorubicin is given

Daunorubicin is given by a slow 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. 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 you are given too much (overdose)

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

If you think you may have been given too much Daunorubicin, immediately telephone your doctor or the Poisons Information Centre (Phone Australia 13 11 26) for advice or go to Accident and Emergency at your nearest hospital.

Ask your doctor if you have any concerns.

Your doctor has information on how to recognise and treat an overdose.

While you are being treated with Daunorubicin

Things you must do

Keep all your doctor's appointments.

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

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

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

Tell your doctor 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.

If you have the potential to fall pregnant, you should take effective contraception during treatment with daunorubicin and for at least 27 weeks after the final dose. If your male partner is being treated with daunorubicin, you must take an effective contraception during his treatment and for at least 14 weeks after the final dose.

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

You are advised to seek doctor consultation on fertility preservation before treatment with Daunorubicin

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Daunorubicin.

Like other medicines, Daunorubicin can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

Ask your doctor, nurse or pharmacist to answer any questions that you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- flushing of the face (hot and red)
- nausea, vomiting, diarrhoea, abdominal pain
- dark areas on the nails and skin
- hair loss
- reddish urine.

These are more common side effects of Daunorubicin.

Tell your doctor immediately or go to your nearest hospital emergency department if you notice any of the following:

- infections, fever, severe chills, sore throat, mouth ulcers
- 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.

These are serious side effects and may be fatal. You may need urgent medical attention.

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

Tell your doctor if you notice any other effects.

Some side effects may only be seen by your doctor.

After treatment with Daunorubicin

Storage

It is kept refrigerated between 2°C to 8°C in a dark place to protect it from light.

Product Description

What it looks like

Daunorubicin is a clear red solution supplied in a plastic vial.

Ingredients

Daunorubicin contains daunorubicin hydrochloride as the active ingredient (equivalent to 2 mg of daunorubicin in each mL of injection). It also contains sodium chloride and Water for Injections.

It does not contain a preservative.

Supplier

Pfizer Australia Pty Ltd
SYDNEY, NSW.

Toll Free Number: 1800 675 229.
www.pfizer.com.au.

Australian Registration Number

20 mg/10 mL - AUST R 12723.

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