PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DAUNOBLASTIN® 20 mg injection

Daunorubicin hydrochloride

Contains sugar alcohol (mannitol)

Each vial contains 100 mg mannitol

Read all of this leaflet carefully before you are given DAUNOBLASTIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DAUNOBLASTIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DAUNOBLASTIN is and what it is used for
2. What you need to know before you are given DAUNOBLASTIN
3. How to receive DAUNOBLASTIN
4. Possible side effects
5. How to store DAUNOBLASTIN
6. Contents of the pack and other information

1. What DAUNOBLASTIN is and what is it used for

DAUNOBLASTIN belongs to a group of anti-cancer medicines known as cytotoxic anthracycline antibiotics. It is used for chemotherapy either alone or in combination with other anti-cancer medicines to treat leukaemia (cancer of the blood and bone marrow). It works by preventing the growth of cancer cells and eventually destroying them.

2. What you need to know before you are given DAUNOBLASTIN

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DAUNOBLASTIN should not be administered to you:

- if you are hypersensitive (allergic) to daunorubicin hydrochloride, other medicines from the same group (anthracyclines or anthracenediones) or any of the other ingredients of DAUNOBLASTIN (listed in section 6)
- if you have long-term, reduced bone marrow function (blood cell production)
- if you have a low blood count following previous chemotherapy or radiotherapy
- if you have heart disease or heart problems, have recently had a heart attack, experienced chest pain or have a severe form of irregular heartbeat (dysrhythmia)
- if you have previously received the total permissible dose of DAUNOBLASTIN or any other medicine from the same group
- if you have severe infections
- if you have severe liver or kidney problems
- if you are pregnant or breastfeeding
- if you have mouth ulcers

Warnings and precautions

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

The elderly, children and infants are at the greatest risk of heart failure when being treated with DAUNOBLASTIN. 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.

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 DAUNOBLASTIN dose if necessary.

Tell your doctor if you are having or have had radiotherapy or if you are having or have had treatment with other anti-cancer medicines.

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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 DAUNOBLASTIN 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.

Other medicines and DAUNOBLASTIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and DAUNOBLASTIN may interfere with each other. These include:

- medicines used to treat a variety of heart conditions (e.g. calcium channel blockers). Your heart function may need to be monitored more frequently throughout your treatment with DAUNOBLASTIN if you are taking these medicines.
- other anti-cancer medicines including cyclophosphamide and doxorubicin. Certain anti-cancer medicines received either before or during your treatment with DAUNOBLASTIN may increase the risk of heart function disorders. Receiving DAUNOBLASTIN and cyclophosphamide at the same time may also increase the risk of a type of bladder inflammation that can cause urinary tract pain and blood in the urine.
- medicines used to treat gout, such as allopurinol, colchicine, probenecid and sulphinpyrazone. A different dose of medicines used to treat gout may be required during your treatment with DAUNOBLASTIN because DAUNOBLASTIN may increase the levels of uric acid in your blood.
- other medicines that affect bone marrow function. A different dose of DAUNOBLASTIN may be required if you are being treated with these medicines.
- medicines which may cause liver problems. Receiving DAUNOBLASTIN and these medicines at the same time may increase your risk of liver function disorders.

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- some vaccines (injections to prevent you getting a certain disease). Treatment with DAUNOBLASTIN may interfere with how your immune system responds to certain vaccines and may increase risk of side effects from certain vaccines.

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving DAUNOBLASTIN.

DAUNOBLASTIN may affect the development of your unborn baby and should not be administered if you are pregnant.

It is not known whether DAUNOBLASTIN passes into breast milk therefore you should not breastfeed your baby during treatment with DAUNOBLASTIN.

Men and women undergoing treatment with DAUNOBLASTIN should use effective birth control methods. If you are a female patient being treated with DAUNOBLASTIN and you have the potential to become pregnant, you should use effective contraception during treatment with DAUNOBLASTIN and for at least 27 weeks after the final dose. If you are a male patient being treated with DAUNOBLASTIN and your female partner has the potential to become pregnant, you must use effective contraception during your treatment with DAUNOBLASTIN for at least 14 weeks after the final dose.

Driving and using machines

There is no specific information available on how DAUNOBLASTIN may affect your ability to drive and use machinery. DAUNOBLASTIN may cause episodes of nausea and vomiting which may indirectly interfere with your ability to drive or use machines. Talk to your doctor or health care provider if you are unsure.

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It is not always possible to predict to what extent DAUNOBLASTIN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DAUNOBLASTIN affects them.

3. How to receive DAUNOBLASTIN

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself DAUNOBLASTIN. It will be given to you by a person who is qualified to do so.

DAUNOBLASTIN is given as a slow intravenous (into a vein) infusion drip.

Your doctor will decide what dose, how often and how long you will receive Daunoblastin. 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 to you at the same time.

If you have the impression that the effect of DAUNOBLASTIN is too strong or too weak, tell your doctor, nurse or health care provider.

If you receive more DAUNOBLASTIN than you should

Since a health care provider will administer DAUNOBLASTIN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use DAUNOBLASTIN

Since a health care provider will administer DAUNOBLASTIN, it is unlikely that the dose will be missed.

4. Possible side effects

DAUNOBLASTIN can have side effects.

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Not all side effects reported for DAUNOBLASTIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DAUNOBLASTIN, please consult your health care provider for advice.

If any of the following happens, stop receiving DAUNOBLASTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty in breathing or any swelling - these are signs of an allergic reaction
- infections, fever, severe chills, sore throat, mouth ulcers - this can be caused by reduced white blood cells
- sores in mouth and on lips, heartburn, or difficulty swallowing
- unusual bruising or bleeding - this may be caused by reduced platelets in your blood
- heart problems (shortness of breath, blue or purple lips or skin, swollen ankles, feet or stomach are signs of heart problems)
- 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 all very serious side effects. If you have them, you may have had a serious reaction to DAUNOBLASTIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- infection in the blood/blood poisoning
- reduced blood cell production (bone marrow failure)
- low blood cell and platelet counts which may cause tiredness, fever or increased risk of bleeding
- nausea
- vomiting
- diarrhoea

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- pain when swallowing (due to inflammation of the food pipe)
- inflammation and ulceration of the mucous membranes lining the digestive tract
- inflammation of the mouth and lips
- mouth ulcers
- stomach pain
- temporary hair loss (after your treatment finishes your hair should grow back)
- general pain
- increased blood bilirubin, aspartate aminotransferase and blood alkaline phosphatase (shown in blood tests)
- abnormal ECG (heart monitor results)
- irregular heartbeat
- increase or decrease of heart rate

Less frequent side effects

- cancer of the white blood cells (acute myeloid leukaemia)
- heart attack

Side effects with unknown frequency

- septic shock (an infection in your blood that can cause changes in how you feel and how your organs work). Symptoms of septic shock may include feeling dizzy, cold, clammy and pale skin, chills, difficulty breathing, feeling confused.
- dehydration
- high levels of uric acid in the blood (symptoms of which may be pain and swelling of the joints)
- reduced blood flow to the heart resulting in chest pain (angina pectoris), thickening/hardening of the heart muscle, inflammation in and around the heart, abnormal/irregular heart rhythm
- flushing of the face (hot and red)
- shock (symptoms of shock may include weakness, fast heart rate, fast breathing, sweating, anxiety and increased thirst)

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- thickening of the vein if frequently used for the site of injection
- lack of oxygen to bodily tissues
- colitis (inflammation of the colon and rectum)
- inflammation of the skin (contact dermatitis)
- sunburn type rash at the site of radiation treatment
- discolouration of skin and nails
- itchy bumps on your skin
- red coloured urine (lasts 1 - 2 days after treatment)
- absence of menstruation in women
- low sperm count in men
- death

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DAUNOBLASTIN.

5. How to store DAUNOBLASTIN

Store all medicines out of reach of children.

Freeze-dried product

Store at or below 25 °C and protect from light.

Reconstituted solution

Stable for 24 hours when stored at room temperature (or below 25 °C).

Stable for 48 hours when refrigerated (2 °C - 8 °C).

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6. Contents of the pack and other information

What DAUNOBLASTIN contains

- The active substance is daunorubicin hydrochloride. Each vial contains 20 mg daunorubicin hydrochloride.

- The other ingredient is mannitol.

What DAUNOBLASTIN looks like and contents of the pack

Orange-red freeze-dried cake.

A colourless glass vial containing 20 mg daunorubicin hydrochloride.

Holder of Certificate of Registration

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This leaflet was last revised in

01 October 2025

Registration number

V/26/239

Viewed on: Thursday, April 16, 2026 - 9:13:35 AM Eastern Time