

DARAZ 200

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DARAZ 200 powder for solution for injection/infusion

Dacarbazine

Contains mannitol.

Sugar free.

Read all of this leaflet carefully before you are given DARAZ 200

- 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.

What is in this leaflet

1. What DARAZ 200 is and what it is used for.
2. What you need to know before you use DARAZ 200.
3. How to use DARAZ 200.
4. Possible side effects.
5. How to store DARAZ 200.
6. Contents of the pack and other information.

1. What DARAZ 200 is and what it is used for

DARAZ 200 is cytostatic medicine and influences the growth of cancer cells.

DARAZ 200 has been prescribed by your doctor for the treatment of cancer, such as:

- advanced malignant melanoma (skin cancer);

- soft tissue sarcoma (cancer of muscles, fat, fibrous tissue, blood vessels or other supporting tissue of the body);
- Hodgkin's disease (cancer of the lymphatic tissue).

DARAZ 200 can be used in combination with other cytostatic medicines to treat other cancers, including cancer of the colon, ovary, breast, lung or testicles.

2. What you need to know before you use DARAZ 200

DARAZ 200 should not be administered to you:

- if you are hypersensitive (allergic) to dacarbazine or any of the other ingredients of DARAZ 200 (see WHAT DARAZ 200 CONTAINS);
- if you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility);
- if you have been diagnosed with leukopenia or thrombocytopenia (the number of white blood cells and/or platelets in your blood is too low);
- if you have a severe liver or kidney disease.

Warnings and precautions

Take special care with DARAZ 200:

- DARAZ 200 may only be administered to you under the supervision of a medical practitioner, who specialised in oncology and has the facilities for regular monitoring, during and after therapy.
- Before each administration, you will have blood tests to check that you have enough blood cells to receive DARAZ 200. Your liver and kidney function will also be monitored.
- You should not receive a live vaccine if you are having DARAZ 200 treatment. This is because DARAZ 200 may weaken your immune system and make you more likely to catch a serious infection.
- If you are male, you should take contraceptive measures during and for 6 months after stopping DARAZ 200 treatment (see Pregnancy, breastfeeding and fertility).

Children and adolescents

DARAZ 200 should not be used in paediatric patients, since no data are available.

Other medicines and DARAZ 200

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

Tell your doctor or pharmacist if you are currently using:

- Radiation treatment or other medicines to reduce tumour growth (chemotherapy). Using these medicines with DARAZ 200 can increase the damage to your bone marrow.
- Other medicines that are metabolised by a system of liver enzymes called cytochrome P450.
- Methoxypsoralen (used for skin problems such as psoriasis and eczema).
- Anticoagulants (used to prevent formation of blood clots).
- Phenytoin (used to treat seizures).
- Ciclosporin or tacrolimus (used to lower your body's immune reaction).
- Fotemustine (used for the treatment of skin cancer).
- Medicines that can cause liver damage or alcohol.
- You should not receive a live vaccine if you are being treated with DARAZ 200 and during 3 months following completion of treatment with DARAZ 200. This is because DARAZ 200 may weaken your immune system and make you more likely to catch a serious infection.

DARAZ 200 with food, drink and alcohol

Do not use alcohol during your treatment with DARAZ 200.

Pregnancy, breastfeeding and fertility

DARAZ 200 must not be given if you are pregnant or breastfeeding.

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 taking DARAZ 200.

If you are a female, you must use an effective method of contraception during treatment with DARAZ 200.

If you are a male, you should continue to use effective contraception during and for at least 6 months after treatment with DARAZ 200 has stopped.

If you are thinking of becoming pregnant or of breastfeeding, discuss it with your doctor first.

Driving and using machines

DARAZ 200 can affect your central nervous system or cause side effects such as nausea and vomiting. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how DARAZ 200 affects you.

3. How to use DARAZ 200

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

DARAZ 200 will be given to you under the direction of a doctor specialised in oncology (cancer treatment) or haematology (the study of diseases of the blood). You will be monitored regularly, during and after your treatment, for any signs of side effects.

Dacarbazine, as in DARAZ 200, is a substance sensitive to light exposure. The doctor or healthcare provider administering DARAZ 200 to you will make sure that DARAZ 200 is protected from exposure to daylight during administration.

Your doctor will calculate the dose you will be given. This will depend on the type of cancer you have and how advanced it is, your body surface area, blood counts and other anticancer medicines or treatments you are currently having. Your doctor will also decide how long DARAZ 200 will be given to you.

Your doctor may change the dose and frequency of dosing, depending on your blood test results, your general condition, further therapies and your response to DARAZ 200.

If you have any questions about your treatment, ask your health care provider.

If you have the impression that the effect of DARAZ 200 is too strong or too weak, tell your doctor or pharmacist.

If you receive more DARAZ 200 than you should

Since a healthcare provider will administer DARAZ 200, he/she will control the dosage. However, in the event of overdosage, your doctor will manage any symptoms of the overdosage.

If you forget to receive DARAZ 200

Since a health care provider will administer DARAZ 200, it is unlikely that the dose will be missed. Tell your health care provider if you suspect that you have missed your DARAZ 200 dose.

4. Possible side effects

DARAZ 200 can have side effects.

Not all side effects reported for DARAZ 200 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DARAZ 200, please consult your health care provider for advice.

If any of the following happens, stop receiving DARAZ 200 and tell your doctor immediately:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DARAZ 200. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- signs of recurrent infections, such as fever or sore throat;
- unexplained bruising or bleeding;
- fits (convulsions);
- yellowing of your skin and eyes, dark urine and tiredness, which may be symptoms of liver problems;
- kidney problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- anaemia (feeling tired, shortness of breath, pale skin);
- loss of appetite (anorexia), feeling sick (nausea) and being sick (vomiting) all of which may be severe.

Less frequent:

- headaches, confusion, lack of energy;
- abnormal sensations of the face (facial paraesthesia) shortly after the injection;
- impaired vision;
- diarrhoea;
- flushing of the face shortly after injection;
- hair loss, increased skin colouring (hyperpigmentation), sensitivity to light (photosensitivity) of the skin, hives;
- flu-like symptoms with exhaustion, chills, fever and muscular pain;
- application site irritation;
- increased liver enzymes, blood lactate dehydrogenase, blood creatinine or blood urea when tests are done.

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 or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of DARAZ 200.

5. How to store DARAZ 200

Before reconstitution:

Store between 2 °C and 8 °C.

After reconstitution:

From a microbiological point of view, DARAZ 200 should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

After reconstitution (with 19,7 mL sterile water for injection):

Store between 2 °C and 8 °C for up to 72 hours and at or below 25 °C for up to 8 hours.

After dilution of the reconstituted solution (with 150 – 250 mL 5 % dextrose or 0,9 % sodium chloride for injection):

- Store between 2 °C and 8 °C for up to 24 hours and at or below 25 °C for up to 8 hours.
- Protect from light (before and after reconstitution).
- Discard any unused portion.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DARAZ 200 contains

Each 20 mL vial contains 200 mg dacarbazine.

After reconstitution DARAZ 200 contains 10 mg/mL dacarbazine.

The other ingredients are citric acid monohydrate (pH adjuster) (E330), D-mannitol (E421) and water for injection.

What DARAZ 200 looks like and contents of the pack

White to pale yellow, freeze-dried cake.

20 mL amber type 1 glass vial closed with a grey chlorobutyl rubber stopper and sealed with an

aluminium seal and a red flip-off cap, packed in an outer carton.

Pack size: 10 vials.

Holder of certificate of registration

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