

1.3.2 Patient Information Leaflet

SCHEDULING STATUS

S4

DACIN 200 lyophilised powder for I.V. injection

Dacarbazine

Contains mannitol

Read all of this leaflet carefully before you start using DACIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DACIN 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 DACIN is and what it is used for
2. What you need to know before you receive DACIN
3. How to receive DACIN
4. Possible side effects
5. How to store DACIN
6. Contents of the pack and other information

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1. What DACIN is and what it is used for

DACIN is a medicine used in the treatment of cancer.

DACIN helps to stop your cancer cells growing and multiplying.

2. What you need to know before you receive DACIN

You should not receive DACIN:

- if you are hypersensitive (allergic) to dacarbazine or any of the other ingredients of DACIN (listed in Section 6).
- if you are pregnant or are breastfeeding your child.
- if you have a low number of white blood cells (leukopenia) or a low number of platelets (thrombocytopenia). If you suffer from leukopenia, you may get infections more frequently, experience tiredness, weakness and shortness of breath. If you suffer from thrombocytopenia, you may bruise more easily or excessively, you may experience bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots, usually on the lower legs, you may experience prolonged bleeding from cuts, or bleeding from your gums or nose. You may also see blood in your urine or stools.
- if you have severe liver or kidney problems.
- in combination with yellow fever vaccine.

Warnings and precautions

Take special care with DACIN:

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During your treatment several tests will be performed to monitor your response to DACIN, such as:

- Tests performed on you blood to determine the number of red and white blood cells and platelets. This will indicate the response of your bone marrow to the treatment.
- Tests performed to determine your liver function. If you experience symptoms such as fever, stomach pain, enlarged liver or jaundice (a yellow colouring of the skin or eyes caused by too much old red blood cells, called bilirubin in the blood), contact your healthcare professional immediately.
- Tests performed to determine your kidney function.
- You should not be vaccinated with a live vaccine as your immune system will be suppressed. Inactivated vaccines may be used.
- DACIN may increase your risk of thrombosis (a blood clot inside a blood vessel, obstructing the flow of blood). Your healthcare professional may prescribe medicine for you to prevent this occurrence.
- You may experience severe stomach reactions, please inform you healthcare professional if this occurs.
- You may experience pain at the injection site.
- Men who are being treated with DACIN are advised to take reliable contraceptive measures during therapy and for 6 months after the end of therapy (refer to the section “Pregnancy and lactation” below).
- DACIN is not recommended for use in children and adolescents as safety and efficacy have not been established.

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DACIN will be given to you by a medical practitioner experienced in administering anti-cancer medicines. He/she will monitor you carefully during and after treatment with DACIN.

Other medicines and DACIN

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

DACIN can affect the way some other medicines work. Some other medicines can also affect the way DACIN works.

Do not receive DACIN and tell your healthcare professional if you are using any of the following:

- Phenytoin – for fits (seizures);
- Yellow fever vaccine.

Tell your healthcare professional if you are using or receiving any of the following:

- Live vaccines – You should not receive a “live” vaccine if you are receiving DACIN. This is because DACIN may weaken your immune system and make you more likely to get a serious infection;
- Ciclosporin or tacrolimus (medicines used after having a transplant);
- Fotemustine (a medicine used in cancer treatment);
- Medicines which could damage your liver, such as other medicines that are metabolised by a system of liver enzymes called cytochrome P450;

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- Warfarin (a medicine used to thin the blood). Your doctor may need to do your blood test (INR) more often;
- Radiation treatment or other medicines to reduce tumour growth (chemotherapy). Using these medicines with DACIN can increase the damage to your bone marrow.
- Methoxypsoralen – for skin problems such as psoriasis and eczema. Receiving DACIN with Methoxypsoralen can make you more sensitive to sunlight (photosensitisation).

If any of the above apply to you (or if you are not sure), please tell your healthcare professional before receiving DACIN.

DACIN with food and drink:

- Do not eat just before receiving DACIN. This could make you feel less sick or be less sick.
- Do not drink alcohol during your treatment.

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 healthcare provider for advice before you receive DACIN.

Do not receive DACIN if you are pregnant or planning to become pregnant. This is because the medicine can damage your unborn child.

Do not breastfeed during your treatment with DACIN.

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During treatment women need to use a reliable method of contraception, such as a contraceptive pill or a barrier method, e.g condom. If you become pregnant, tell your doctor straight away.

Women of childbearing potential must use effective contraception during treatment with DACIN and for 6 months after receiving the last dose.

Men who are being treated with DACIN also need to use a reliable method of contraception, such as a condom, for up to 3 months after the end of therapy. Men are advised not to father a child during the treatment, and up to 3 months thereafter.

Driving and using machines

DACIN may make you feel drowsy/sleepy and impair your vision. You may also feel or be sick. Do not drive because DACIN could interfere with your ability to drive safely. Do not operate any tools or machines.

3. How to receive DACIN

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

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

The amount you are given is worked out depending on your size (m² body surface area).

Your doctor will tell you how long your treatment with DACIN will last.

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

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If you receive more DACIN than you should

Since a healthcare professional will administer DACIN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

- If an overdose is suspected, the numbers of your blood cells will be checked and supportive measures such as transfusions may be required.
- An overdose would cause severe damage to your bone marrow (bone marrow toxicity). This can lead to a complete loss of function of your bone marrow (bone marrow aplasia). This can be delayed by up to 2 weeks.
- Episodes of low blood pressure can occur with doses higher than the recommended. Your doctor will treat these episodes.

If you missed a dose of DACIN

Do not receive a double dose to make up for the forgotten dose. Contact your doctor to schedule a new time for you to receive the dose you missed.

4. Possible side effects

DACIN can have side effects.

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

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

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

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

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

- flu-like symptoms such as tiredness, chills, fever or muscle pain;
- feeling unwell (malaise);
- fits (seizures);
- adverse effects on your blood, such as:
 - anaemia (decreased red blood cells).
 - leukopenia (decreased white blood cells).
 - thrombocytopenia (decreased platelets).
 - bone marrow suppression (decreased formation of all blood cells in the bone marrow).
- blockage of a vein in your liver (also called Budd-chiari syndrome);
- liver tissue damage (necrosis) due to blockage of a vein in your liver. The signs include fever, stomach pain, yellow eyes and skin (jaundice).
- diverse effects on your blood, such as:

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- pancytopenia (all blood cells decreased);
- agranulocytosis (marked decrease in one type of white blood cell called a granulocyte).

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

Tell your doctor if you notice any of the following (these side effects occur more frequently):

- injection site irritation;
- loss of appetite (anorexia);
- feeling sick or being sick.

Tell your doctor if you notice any of the following (these side effects occur less frequently):

- abnormal kidney function;
- increased liver enzymes (shown in tests);
- liver damage (hepatotoxicity);
- dark patches on your skin (hyperpigmentation);
- increased sensitivity of your skin to sunlight (photosensitivity);
- hair loss (alopecia);
- feeling confused;
- flushed face;
- transient rash;
- impaired or blurred vision;

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- red skin (erythema), a rash with spots and blisters (maculopapular exanthema) or a nettle rash (urticaria);
- feeling sleepy;
- headache;
- pins and needles sensation in the face;
- diarrhoea.

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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 DACIN.

5. How to store DACIN

Store all medicines out of reach of children.

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- Store at or below 25 °C. Store in the original package in order to protect from light.
- Do not receive DACIN if the solution is cloudy or has bits floating in it.
- *Shelf life of the reconstituted solution*

Chemical and physical in-use stability has been demonstrated for 8 hours at room temperature and protected from light and for 5 days at 2 °C to 8 °C and protected from light. From a microbiological point of view, the reconstituted solution should be used immediately.

If the reconstituted solution is not used immediately, the duration and conditions of storage are the responsibility of the user. The reconstituted solution should not be stored for longer than 24 hours in a refrigerator (2 °C to 8 °C) and protected from light, unless the reconstitution has taken place under controlled and validated aseptic conditions.

- *Shelf life of the diluted solution for infusion*

Chemical and physical in-use stability has been demonstrated for 8 hours at room temperature and protected from light and for 5 days at 2 °C to 8 °C and protected from light. From a microbiological point of view, the diluted solution for infusion should be used immediately.

If the diluted solution for infusion is not used immediately, the duration and conditions of storage are the responsibility of the user. The diluted solution for infusion should not be stored for longer than 24 hours in a refrigerator (2 °C to 8 °C) and protected from light, unless the reconstitution and dilution have taken place under controlled and validated aseptic conditions.

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- From a microbiological point of view, the reconstituted solution should be used immediately.
- Do not use after the expiry date stated on the label /carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

DACIN contains

- The active substance is dacarbazine.
Each vial contains 200 mg dacarbazine.
- The other ingredients are citric acid monohydrate and mannitol (E421).

What DACIN looks like and contents of the pack

White lyophilised powder.

The reconstituted solution is a clear, pale yellow solution, with no visible particles, which dissolves within one minute.

Contents of the pack:

10 Single use vials in an outer cardboard box. The vials are brown, type I glass vials, with a grey rubber stopper and a red plastic flip off cap.

Holder of Certificate of Registration

KEY ONCOLOGICS (PTY) LTD

39 Eleventh Avenue

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Houghton Estate

2198

Johannesburg

South Africa

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Access to the corresponding Professional Information

Can be obtained from the SAHPRA website: www.sahpra.org.za.

Namibia: NS2: 19/26/0049