

DBL™ Dacarbazine for Injection

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 being treated with DBL Dacarbazine for Injection?

DBL Dacarbazine for Injection contains the active ingredient dacarbazine. DBL Dacarbazine for Injection is used to treat some types of cancers: melanoma (skin cancer) that have spread and sarcoma (cancer which occurs in bone and/or soft tissue).

For more information, see Section [1. Why am I being treated with DBL Dacarbazine for Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Dacarbazine for Injection?

You should not be given DBL Dacarbazine for Injection if you have ever had an allergic reaction to dacarbazine or any of the ingredients listed at the end of the CMI, are pregnant, or are breastfeeding. Talk to your doctor

if you have any other medical conditions, take any other medicines, or plan to become pregnant.

For more information, see Section [2. What should I know before treatment with DBL Dacarbazine for Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Dacarbazine for Injection 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 DBL Dacarbazine for Injection given?

The dose of medicine given to you will depend on your condition, weight, height, how well your kidneys and liver are working and whether you are being given any other medicines at the same time.

More instructions can be found in Section [4. How is DBL Dacarbazine for Injection given?](#) in the full CMI.

5. What should I know while being treated with DBL Dacarbazine for Injection?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist, pharmacist and
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	<p>nurse who are treating you that you are being given this medicine.</p> <ul style="list-style-type: none"> ● If you plan to be vaccinated within a year of being given DBL Dacarbazine for Injection, tell the doctor before you are vaccinated. ● Males should use effective contraception during and for at least 3 months after stopping treatment. Females should use effective contraception while receiving this medicine and for at least 6 months after stopping treatment. If you become pregnant while you are being given DBL Dacarbazine for Injection, tell your doctor immediately. ● Keep all of your doctor's appointments so your progress can be checked.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not breastfeed while you are being treated

	with DBL Dacarbazine for Injection.
Driving or using machines	<ul style="list-style-type: none"> Do not drive or operate machinery until you know how DBL Dacarbazine for Injection affects you. Dacarbazine may affect your ability to drive or operate machinery as it can cause nausea, vomiting, dizziness, tiredness and confusion in some people.

For more information, see Section [5. What should I know while being treated with DBL Dacarbazine for Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include nausea, vomiting, diarrhoea, skin rash or itching, hair loss, headache, tiredness, flushing in the face, dizziness upon standing, blurred vision; confusion; tingling, numbness of the skin or pins and needles sensation. Serious side effects include severe allergic reaction (shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin); signs of infection (fever, chills, muscle pain, sore or inflamed mouth); unusual bleeding or bruising (including black stools, blood in your stools or urine

or pinpoint red spots on your skin); pain or irritation at the injection site; seizures; severe abdominal pain or swelling and yellowing of the skin or eyeballs.

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.

DBL™ Dacarbazine for Injection

Active ingredient(s): *dacarbazine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Dacarbazine for Injection. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using DBL Dacarbazine for Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Dacarbazine for Injection?](#)
- [2. What should I know before treatment with DBL Dacarbazine for Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Dacarbazine for Injection given?](#)
- [5. What should I know during treatment with DBL Dacarbazine for Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Dacarbazine for Injection?

DBL Dacarbazine for Injection contains the active ingredient dacarbazine. DBL Dacarbazine for Injection belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine. Dacarbazine works by killing cancer cells and stopping cancer cells from growing and multiplying.

DBL Dacarbazine for Injection is used to treat some types of cancers: melanoma (skin cancer) that have spread and sarcoma (cancer which occurs in bone and/or soft tissue).

2. What should I know before treatment with DBL Dacarbazine for Injection?

Warnings

DBL Dacarbazine for Injection should not be given to you if:

1. you are allergic to dacarbazine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

2. you are pregnant or breastfeeding.

3. you have had any blood disorder with low numbers of red blood cells, white blood cells, or platelets.

Check with your doctor if you have:

- any problems with your liver.
- any problems with your kidney.
- an infection, including shingles and chickenpox or a recent exposure to chickenpox.
- a low immune system due to other medicines or treatments.

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Tell your doctor or dentist if you intend having any dental work while being treated with DBL Dacarbazine for Injection.

DBL Dacarbazine for Injection may increase the incidence of infection, delay healing and gum bleeding. It is therefore recommended that any dental work be completed prior to starting dacarbazine treatment or delayed until blood counts have returned to normal.

Tell your doctor if you intend to receive any vaccinations. Do not receive certain vaccines while you are being treated with DBL Dacarbazine for Injection, and for at least one year after you stop treatment.

DBL Dacarbazine for Injection may lower your body's resistance and if you receive certain vaccines with it, you may get the serious infection the vaccination is meant to prevent.

In addition, other people in close contact with you (such as other persons living in your home) should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

It may be helpful to restrict food intake for 4 - 6 hours prior to being treated with DBL Dacarbazine for Injection as this may reduce the severity of nausea and vomiting you may experience, especially during the first two days of treatment. Discuss medicines that may also help with sickness with your doctor prior to treatment with DBL Dacarbazine for Injection.

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

Talk to your doctor if you are pregnant or plan to become pregnant.

You should not be given DBL Dacarbazine for Injection if you are pregnant or intend to become pregnant.

DBL Dacarbazine for Injection may cause birth defects. It is recommended that females use effective contraception while receiving this medicine and for at least 6 months after stopping treatment. Males should

use effective contraception during and for at least 3 months after stopping treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not breastfeed while you are being treated with DBL Dacarbazine Injection.

It is not known whether dacarbazine passes into breast milk.

3. What if I am taking other medicines?

Tell your doctor, nurse 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/treatments may interfere with DBL Dacarbazine for Injection and affect how it works.

- any medicines which suppress your immune system such as azathioprine, ciclosporin and tacrolimus.
- some medicines used to treat gout, such as allopurinol.
- medicines used to treat epilepsy such as phenytoin.
- barbiturates (such as phenobarbitone, primidone and thiopental sodium) used to treat seizures, help with sleep or as a general anaesthetic for surgery.
- rifampicin, an antibiotic used to treat tuberculosis (TB).
- levodopa, a medicine used in the treatment of Parkinson's disease.

- other medicines used to treat cancers (such as mercaptopurine, fotemustine or interleukin-2), radiation therapy or any other treatment which lowers your immune system.
- certain vaccines (such as live vaccines).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Dacarbazine for Injection.

4. How is DBL Dacarbazine for Injection given?

How much is given

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, height, how well your kidneys and liver are working and whether you are being given any other medicines at the same time.

How long it is given for

DBL Dacarbazine for Injection may be given alone or in combination with other drugs.

Several courses of dacarbazine therapy may be needed, depending on your response to treatment. Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.

How it is given

DBL Dacarbazine for Injection is given as slow infusion ("drip") into a vein by a doctor or nurse over the period of about one minute.

If you believe you have been given too much DBL Dacarbazine for Injection

As DBL Dacarbazine for Injection will be given to you in hospital or under the supervision of your doctor, it is very unlikely that you will receive an overdose.

If you think that you have been given too much DBL Dacarbazine for Injection or experience severe side effects, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know during treatment with DBL Dacarbazine for Injection?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given DBL Dacarbazine for Injection.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are taking this medicine. It may affect other medicines used during surgery.

If you plan to be vaccinated within a year of being given DBL Dacarbazine for Injection, tell the doctor before you are vaccinated.

If you become pregnant while you are being given DBL Dacarbazine for Injection, tell your doctor immediately.

Keep all of your doctor's appointments, and ensure you have all tests your doctor asks you to, so your progress can be checked.

Things you should not do

- You should not breastfeed while you are being treated with DBL Dacarbazine for Injection.

Things to be careful of

DBL Dacarbazine for Injection can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who are unwell or have infections.
- Be careful when using a toothbrush, dental floss or toothpick. Your doctor, dentist or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done.
- Be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters.
- Avoid contact sports or other situations where bruising or injury may occur.

Your body breaks down dacarbazine and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of

water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.

- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Dacarbazine for Injection affects you.

DBL Dacarbazine for Injection may affect your ability to drive or operate machinery as it can cause nausea, vomiting, dizziness, tiredness and confusion in some people. Make sure you know how you react to dacarbazine before you drive a car, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

No information is available.

Looking after your medicine

DBL Dacarbazine for Injection will be stored appropriately in the hospital ward or in the pharmacy.

6. Are there any side effects?

All medicines can have side effects. Some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none">• nausea, vomiting• diarrhoea• skin rash or itching• hair loss, particularly on the scalp• headache• tiredness• flushing in the face• dizziness upon standing (due to a fall in blood pressure)• blurred vision• confusion• tingling, numbness of the skin or pins and needles sensation	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<ul style="list-style-type: none"> ● increased sensitivity of skin to the sun which means you may burn more easily 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin (severe allergic reaction) ● signs of infection, such as fever, chills, muscle pain, sore, ulcerated or inflamed mouth ● unusual bleeding or bruising (including black stools, blood in your stools or urine or pinpoint red spots on your skin) ● pain or irritation at the injection site 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● seizures ● severe abdominal pain or swelling ● yellowing of the skin or eyeballs 	

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

Other side effects not listed here may occur in some people.

Some of these side effects (for example, changes in blood cell count, blood pressure, heart and liver function) can only be found when your doctor does tests from time to time to check your progress.

The benefits and side effects of dacarbazine may take some time to occur. Therefore, even after you have finished your treatment with DBL Dacarbazine for Injection you should tell your doctor immediately if you notice any of the side effects listed in this section.

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/safety/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 DBL Dacarbazine for Injection contains

Active ingredient (main ingredient)	dacarbazine
Other ingredients (inactive ingredients)	citric acid monohydrate mannitol

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

What DBL Dacarbazine for Injection looks like

DBL Dacarbazine for Injection is a white or very pale yellow powder. It contains 200 mg dacarbazine supplied in an amber glass vial. It is available in single packs of 1 vial.

AUST R 39954.

Who distributes DBL Dacarbazine for Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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