

DBL™ Dacarbazine for Injection

Dacarbazine (da-CAR-ba-zeen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Dacarbazine for Injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you being given DBL™ Dacarbazine for Injection against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place.

You may need to read it again.

What DBL™ Dacarbazine for Injection is used for

Dacarbazine belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine. Dacarbazine belongs to a group of cytotoxics known as 'alkylating agents'.

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 melanomas (skin cancers) and a type of cancer called sarcoma.

Your doctor may have prescribed DBL™ Dacarbazine for Injection for another reason.

Ask your doctor if you have any questions about why DBL™ Dacarbazine for Injection has been prescribed for you.

This medicine may be used in combination with other medicines to treat cancer.

DBL™ Dacarbazine for Injection is available only with a doctor's prescription.

Before you are given DBL™ Dacarbazine for Injection

When you must not be given it

You must not be given DBL™ Dacarbazine for Injection if you have an allergy to dacarbazine or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to DBL™ Dacarbazine for Injection may include:

- 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.

You should not be given DBL™ Dacarbazine for Injection if you have or have had any of the following medical conditions:

- low white blood cell (WBC) count
- problems with blood clotting
- any blood disorder with a reduced number of red blood cells, white blood cells, or platelets.

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.

You should not be given dacarbazine if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, dacarbazine is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Dacarbazine may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are receiving this medicine and for at least 12 weeks after you stop. Your doctor will discuss this with you.

Many cancer medicines can cause infertility. Your doctor should discuss this issue with you before you begin therapy with DBL™ Dacarbazine for Injection.

You should not be given DBL™ Dacarbazine for Injection if you are breast-feeding.

It is not known whether dacarbazine passes into breast milk. However, breast-feeding is not recommended while you are being treated with dacarbazine.

If you are not sure whether you should be given DBL™ Dacarbazine for Injection, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- kidney disease
- liver disease
- an infection, including shingles and chickenpox or a recent exposure to chickenpox
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy).

Tell your doctor or dentist if you intend having any dental work while being treated with dacarbazine.

Dacarbazine may increase the incidence of infection, delayed healing and gum bleeding. It is therefore recommended that any dental work be completed prior to starting dacarbazine treatment.

If you have not told your doctor about any of the above, tell them before you start being treated with dacarbazine.

Taking other medicines

Tell your doctor or pharmacist 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 dacarbazine may interfere with each other. These include:

- any medicines which suppress your immune system such as azathioprine

- some medicines used to treat gout, such as allopurinol
- medicines used to treat epilepsy such as phenytoin and barbiturates
- rifampicin, an antibiotic used to treat tuberculosis (TB)
- levodopa, a medicine used in the treatment of Parkinson's disease
- other medicines used to treat cancer (such as mercaptopurine or fotemustine), radiation therapy or any other treatment which lowers your immune system
- some vaccines (ask your doctor).

These medicines may be affected by dacarbazine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Do not have any immunisations (vaccinations) while you are being treated with dacarbazine, and for at least one year after you stop treatment, without your doctor's approval.

Dacarbazine may lower your body's resistance and there is a chance that you may get the infection the immunisation is meant to prevent.

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given Dacarbazine for Injection.

How DBL™ Dacarbazine for Injection is given

How much is given

Your doctor will decide what dose of dacarbazine you will receive. This depends on your condition and other factors, such as your weight, height and if you are being given any other chemotherapy medicines.

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.

Ask your doctor if you want to know more about the dose of dacarbazine you receive.

How it is given

DBL™ Dacarbazine for Injection is given as a slow injection into a vein.

DBL™ Dacarbazine for Injection must only be given by a doctor or nurse.

How long it is given for

Dacarbazine is usually given in one of two different ways:

- It may be given as a small daily dose for 10 days and repeated if needed, after 4 weeks.

- It may be given as a larger daily dose for 5 days and repeated if needed, after 3 weeks.

Each group of smaller doses is called a 'cycle' of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you take too much (overdose)

As Dacarbazine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given dacarbazine, tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand).

You may need urgent medical attention.

Symptoms of a dacarbazine overdose include the side effects listed below under 'Side Effects', but are usually of a more severe nature.

While you are being given DBL™ Dacarbazine for Injection

Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up cycles of dacarbazine at the appropriate times to get the best effects from your treatments.

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given dacarbazine.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given dacarbazine.

If you plan to be vaccinated within a year of being given dacarbazine, tell the doctor before you are vaccinated.

If you become pregnant while you are being given dacarbazine, tell your doctor immediately.

Dacarbazine 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 with infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever or chills, cough or hoarse throat, lower back or side pain, or find it painful or difficult to urinate;
- Check with your doctor immediately if you notice any unusual bleeding or bruising, black stools, blood in urine or stools or pinpoint red spots on your skin;

- 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.

Things to be careful of

Be careful driving or operating machinery until you know how dacarbazine affects you.

As with some other medicines, dacarbazine may cause 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 if you are dizzy or light-headed. If this occurs do not drive.

If you drink alcohol, dizziness or light-headedness may be worse.

Side effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are being given DBL™ Dacarbazine for Injection.

Like other medicines that treat cancer, dacarbazine may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- nausea, vomiting and loss of appetite
- diarrhoea
- skin rash or itching
- lethargy (tiredness)

- headache.

These are the more common side effects of dacarbazine. Mostly these are mild and short-lived.

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

- signs of infection, such as fever, chills, sore throat or mouth ulcers
- pain or irritation at the injection site
- symptoms of an allergic reaction, such as those listed at the start of this leaflet
- severe abdominal pain
- unusual bleeding or bruising (including blood in your stools or urine)
- problems with urination eg. pain or difficulty
- dizziness upon standing (due to a fall in blood pressure)
- tingling, tremors or pain in your muscles
- blurred vision
- yellowing of the skin or eyeballs
- severe nausea and vomiting
- fits (seizures)
- confusion.

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

Temporary loss of hair, particularly that on the scalp is a less common side effect of dacarbazine and occurs in a small number of patients. The severity of hair loss will depend on the dose of dacarbazine given. It is more common when other anti-cancer medicines are used together with dacarbazine.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

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

After you have been given Dacarbazine for Injection

Storage

DBL™ Dacarbazine for Injection will be stored in the pharmacy or on the ward. Store between 2°C and 8°C. Refrigerate. Do not freeze. Protect from light.

Product description

What it looks like

DBL™ Dacarbazine for Injection is a colourless or pale yellow crystalline powder which will be mixed with Water for Injection before use. It comes in 20 mL amber glass vials.

Ingredients

Active ingredient:

- dacarbazine

Other ingredients:

- citric acid
- mannitol

Dacarbazine for Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Dacarbazine for Injection is available in single packs in the following strength:

- 200 mg vials
AUST R 39954

this leaflet was updated in July 2015.