

Dacarbazine Sandoz®

Dacarbazine powder for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Dacarbazine Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor and pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

WHAT DACARBAZINE SANDOZ IS USED FOR

This medicine is used to treat some types of melanomas (skin cancers) and a type of cancer called sarcoma.

It contains the active ingredient, dacarbazine. 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 also belongs to a group of cytotoxics known as "alkylating agents".

It works by killing cancer cells and stopping cancer cells from growing and multiplying.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU ARE GIVEN DACARBAZINE SANDOZ

When you must not be given it

You must not be given this medicine if you have an allergy to:

- dacarbazine, the active ingredient, or to any of the ingredients listed at the end of this leaflet under Product Description

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing or swallowing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You must not be given this medicine if you have or have had any of the following medical conditions:

- problems with blood clotting
- blood disorder with a reduced number of red blood cells, white blood cells or platelets.

You must not be given this medicine if you are pregnant or breast-feeding.

Like most medicines used to treat cancer, Dacarbazine Sandoz is not recommended for use during pregnancy or breast-feeding. Your

doctor can discuss the risks and benefits with you.

Do not use Dacarbazine Sandoz if the packaging is torn or shows signs of tampering.

Do not use Dacarbazine Sandoz after the expiry date (EXP) printed on the pack has passed.

If you are not sure whether you should be given Dacarbazine Sandoz, talk to your doctor, nurse or pharmacist.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease
- liver disease
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer
- high temperature or an infection, including shingles and chickenpox or a recent exposure to chickenpox. 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 if you intend to become pregnant

Dacarbazine Sandoz 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 Dacarbazine Sandoz 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 Dacarbazine Sandoz.

Tell your doctor if you intend to breast-feed

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

Tell your doctor if you are having radiation therapy or any other treatment which lowers the immune system.

Tell your doctor or dentist if you intend to have any dental work while being treated with Dacarbazine Sandoz.

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.

Your doctor or dentist can tell you how to best take care of your teeth and gums while you are being treated with dacarbazine.

If you have not told your doctor about any of the above, tell him/her before you are given Dacarbazine Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

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

- medicines to treat gout such as probenecid or allopurinol
- medicines to treat epilepsy such as barbiturates or phenytoin
- medicines used to suppress the immune system such as azathioprine, cyclosporin and corticosteroids
- other medicines used to treat cancer such as mercaptopurine or fotemustine
- rifampicin, an antibiotic used to treat tuberculosis (TB)
- levodopa, a medicine used in the treatment of Parkinson's disease
- some vaccines used for immunisation.

These medicines may be affected by Dacarbazine Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines. Your doctor will advise you.

Do not have any immunisations (vaccinations) while you are being treated with Dacarbazine Sandoz, and for at least one year after you stop treatment, without your doctor's approval. Dacarbazine Sandoz 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 have more information on medicines to be careful with or avoid while using Dacarbazine Sandoz.

HOW DACARBAZINE SANDOZ IS GIVEN

Dacarbazine Sandoz will be given to you in hospital by highly trained medical personnel.

Dacarbazine Sandoz can be given as a slow injection into the vein over about one minute.

How often it will be given

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

Dacarbazine Sandoz is usually given as a small daily dose for 10 days and may be repeated every 4 weeks. It may be also given as a larger daily dose for 5 days and may be repeated every 3 weeks.

Several courses of dacarbazine therapy may be needed, depending on your response to the treatment.

Dacarbazine Sandoz may be given alone or in combination with other anticancer medicines.

If your blood cell levels are affected 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.

If you have been given too much (overdose)

As Dacarbazine Sandoz will be 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, immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose may include severe nausea (feeling sick) or vomiting, diarrhoea, confusion, seizures, blurring of vision, lack of energy and headache.

WHILE YOU ARE BEING GIVEN DACARBAZINE SANDOZ

Things you must do

Keep all your doctor's appointments so that 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 Sandoz at the appropriate times to get the best effects from your treatments.

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

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

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

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 using this medicine 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, vomitus 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 (with the toilet lid down) 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.**
- **Washing 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.**
- **Placing 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 Sandoz affects you.

Dacarbazine Sandoz generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Dacarbazine Sandoz may cause blurring of vision, seizures (fits or convulsions), headache, confusion, dizziness, tiredness or drowsiness in some people.

Make sure you know how you react to Dacarbazine Sandoz before you drive a car, operate machinery or do anything that may be dangerous if you are affected.

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Dacarbazine Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

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

- nausea (feeling sick), vomiting
- loss of appetite
- headache
- lethargy (tiredness)
- diarrhoea
- weakness or tiredness
- skin rash or itching
- increased sensitivity to the sun.

These side-effects are usually mild.

If any of the following happen, tell your doctor, pharmacist or nurse or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as a rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- blurred vision
- confusion
- signs of infection, such as fever, chills, sore throat or mouth ulcers
- severe pain or irritation at the injection site
- aching muscles
- unusual bleeding or bruising (including blood in your stools or urine)
- problems with urination, e.g. pain or difficulty
- dizziness upon standing
- tingling, tremors or pain in your muscles
- severe nausea and vomiting
- severe diarrhoea
- yellowing of the skin or eyeballs
- severe abdominal pain
- fits or convulsions (seizures).

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

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.

The benefits and side effects of Dacarbazine Sandoz 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 leaflet.

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

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

AFTER USING DACARBAZINE SANDOZ

Storage

Dacarbazine Sandoz will be stored in the pharmacy or on the hospital ward. The powder for injection is kept in a cool dry place where the temperature stays below 25°C, protected from light.

The solution for injection is kept in a refrigerator where the temperature stays between 2-8°C, protected from light.

PRODUCT DESCRIPTION

What it looks like

Dacarbazine Sandoz is a white to very pale yellow crystalline powder. The reconstituted solution appears as a clear, pale yellow to colourless solution.

Ingredients

Active ingredient:

- Dacarbazine Sandoz 200mg – 200mg dacarbazine

Inactive ingredients:

- citric acid
- mannitol.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Dacarbazine Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Tel: 1800 634 500

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