

DBL™ Bleomycin Sulfate for Injection

Bleomycin Sulfate (blee-oh-MYE-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Bleomycin Sulfate for Injection (DBL™ Bleomycin).

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 has weighed the risks of you being given DBL™ Bleomycin 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™ Bleomycin is used for

DBL™ Bleomycin belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may hear it referred to as chemotherapy medicine.

DBL™ Bleomycin is classified as an anti-tumour antibiotic. It interferes with the growth of cancer cells, which are eventually destroyed.

Your doctor may have prescribed bleomycin for another reason.

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

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

DBL™ Bleomycin is not recommended for use in children, as there have not been enough studies of its effects in children.

Before you are given DBL™ Bleomycin

When you must not be given it

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

Symptoms of an allergic reaction to DBL™ Bleomycin 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™ Bleomycin if you have any of the following conditions:

- problems with blood clotting
- severe lung problems, a lung infection or reduced lung function.

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.

If you are not sure whether you should start treatment with DBL™ Bleomycin, talk to your doctor.

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 are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of treatment with bleomycin during pregnancy.

DBL™ Bleomycin may cause birth defects if either the male or the female is receiving it at the time of conception or if it is used during pregnancy. You should use some form of birth control while you are receiving bleomycin and for at least 12 weeks after stopping. Your doctor will discuss this with you.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Like most antineoplastic medicines, bleomycin is not recommended while you are breast-feeding.

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

- kidney disease
- liver disease
- lung disease.

Tell your doctor if you smoke.

There is a greater chance of DBL™ Bleomycin affecting your lungs if you smoke.

Tell your doctor if you have had radiation therapy for cancer.

There is a greater chance of DBL™ Bleomycin affecting your lungs if you have had radiation therapy, especially to the chest.

If you have not told your doctor or pharmacist about any of the above, tell them before you start treatment with DBL™ Bleomycin.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DBL™ Bleomycin may interfere with each other.. These include:

- digoxin, a medicine used to treat heart failure
- phenytoin, a medicine used to treat epilepsy, fits or seizures
- cisplatin, a medicine used to treat some types of cancer
- oxygen therapy, which may be given to you during surgery
- other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system
- general anaesthetics
- granulocyte colony stimulating factor (such as filgrastim and lenograstim).

These medicines may be affected by DBL™ Bleomycin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Some of these medicines and DBL™ Bleomycin may interfere with each other even if they are not given at the same time. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given DBL™ Bleomycin.

How DBL™ Bleomycin is given

How much is given

Your doctor will decide what dose of DBL™ Bleomycin you will receive. This depends on your condition and other factors, such as your weight and height, kidney function and other chemotherapy medicines you are being given.

DBL™ Bleomycin may be given alone or in combination with other drugs.

Several courses of DBL™ Bleomycin 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 unwanted side effects have been controlled.

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

How it is given

DBL™ Bleomycin should only be given by a doctor or nurse.

DBL™ Bleomycin can be given in a number of different ways:-

- an injection under the skin
- an injection into a muscle
- an injection into a vein
- an injection into an artery.

The first time you are given DBL™ Bleomycin, you will normally receive a small test dose to check that you are not allergic to bleomycin. If no reaction occurs, the full dose will be given.

How long it is given

A course of DBL™ Bleomycin may consist of a dose once or twice weekly, or it may be given as a daily dose for 7 consecutive days. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Overdose

As DBL™ Bleomycin will be given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL™ Bleomycin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of a DBL™ Bleomycin overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are being given DBL™ Bleomycin

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of bleomycin.

Things you must do

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

Your doctor may want to 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 doses of DBL™ Bleomycin 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 DBL™ Bleomycin.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DBL™ Bleomycin. If you become pregnant while you are being treated with DBL™ Bleomycin, tell your doctor immediately.

DBL™ Bleomycin 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, chills, cough, hoarse throat, lower back or side pain, or find it painful or difficult to urinate;
- Be careful when using a toothbrush, dental floss or toothpick. Your doctor, dentist, nurse or pharmacist 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 razor or nail cutters;
- Avoid contact sports or other situations where bruising or injury may occur.

While you are being given DBL™ Bleomycin, your doctor should order regular tests to check the number of blood cells in your blood. The results of these tests will be used to determine the amount of DBL™ Bleomycin you will be given for your next dose.

While you are being given DBL™ Bleomycin your doctor should order regular tests to check how well your kidneys are working.

Your doctor should also order periodic tests to estimate how well your liver is working during treatment with DBL™ Bleomycin.

DBL™ Bleomycin is known to affect the way the lungs work in some patients. This may be serious, therefore your doctor should arrange frequent tests to check how well your lungs are working. Your doctor may also arrange weekly chest X-rays while you are being treated with DBL™ Bleomycin. These should continue for up to 4 weeks after completion of treatment with DBL™ Bleomycin.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Bleomycin affects you.

As with some other medicines, DBL™ Bleomycin may cause dizziness, light-headedness and tiredness in some people. Make sure you know how you react to bleomycin 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 bleomycin.

Like other medicines that treat cancer, DBL™ Bleomycin may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of these 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 or nurse if you notice any of the following and they worry you:

- nausea, vomiting or loss of appetite
- tiredness or weakness
- headaches
- pain and inflammation at the injection site
- rash and other skin conditions such as itchiness, tenderness, altered pain sensation and altered skin colour
- conjunctivitis (infection/ inflammation of the eye)
- soreness or ulceration of the mouth.

These are the more common side effects of DBL™ Bleomycin.

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

- cough and shortness of breath
- fever and chills
- signs of an allergic reaction such as those listed at the start of this leaflet
- disorientation or personality changes
- severe nausea and vomiting
- severe abdominal pain
- chest pain
- severe headache
- severe mouth ulceration and/or anal ulceration
- unusual bleeding or bruising (including blood in your stools or urine)
- painful or difficult urination
- blurred vision or eye pain
- yellowing of the skin or eyes
- fits (seizures).

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

Temporary loss of hair, particularly that on the scalp is a less common side effect of bleomycin and occurs in a small number of patients. The severity of hair loss will depend on the dose of DBL™ Bleomycin given. It is

more common when other anti-cancer medicines are used together with bleomycin.

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 effects of bleomycin may take some time to occur and therefore the side effects may be delayed. It is possible that the unwanted side effects may not occur until months after DBL™ Bleomycin is given. Therefore, even after you have finished receiving your DBL™ Bleomycin treatment you should tell your doctor immediately if you notice any of the side effects listed above.

After you have been given DBL™ Bleomycin

Storage

DBL™ Bleomycin will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product description

What it looks like

DBL™ Bleomycin is a white to cream coloured powder. It must be dissolved in Water for Injections or 0.9% Sodium Chloride solution before use.

Ingredients

Active ingredient:

- Bleomycin Sulfate 15,000 IU (15 units USP) per vial

There are no other ingredients.

DBL™ Bleomycin does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier/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

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