

DBL™ Bleomycin Sulfate 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 Bleomycin Sulfate Injection?

DBL Bleomycin Sulfate Injection contains the active ingredient bleomycin sulfate. DBL Bleomycin Sulfate Injection is a type of medicine called an anti-neoplastic/cytotoxic agent/chemotherapy. It is used to treat cancer of the uterine cervix, penis, testes, immune system, lymphatic system, skin, oesophagus, head, neck and some lung cancers.

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

2. What should I know before treatment with DBL Bleomycin Sulfate Injection?

You should not be given DBL Bleomycin Sulfate Injection if you have ever had an allergic reaction to bleomycin sulfate.

Tell your doctor if you have kidney, liver, lung disease, are having or have had radiation therapy, have had previous treatment for cancer, have lymphatic problems, had a recent infection, take any other medicines; are pregnant, or you or your partner plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with DBL Bleomycin Sulfate Injection and affect how it works. Examples include medicines to treat the heart, seizures/fits, cancer, oxygen therapy and/or general anaesthetic during surgery or medicines to fight infections.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL Bleomycin Sulfate Injection given?

Your doctor will decide how you will receive the DBL Bleomycin Sulfate Injection, how much you will be given and for how long. More instructions can be found in Section [4. How is DBL Bleomycin Sulfate Injection given?](#) in the full CMI.

5. What should I know while using DBL Bleomycin Sulfate Injection?

Things you should do	• Talk to your doctor immediately if you experience certain side effects. Some side effects may be experienced during or after stopping treatment. • Remind any doctor, nurse, dentist, surgeon, anaesthetist or pharmacist you visit that you are being treated with DBL Bleomycin Sulfate Injection. • Tell your doctor immediately if you or your partner become pregnant.
Driving or using machines	• Be careful until you know how DBL Bleomycin Sulfate Injection affects you.
Looking after your medicine	• The hospital will store and dispose of the medicine.

For more information, see Section [5. What should I know while using DBL Bleomycin Sulfate Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects include sudden cough and shortness of breath that may worsen to difficulty breathing/wheezing with fatigue; fever; allergic reaction which may include swelling of the face, lips, tongue or throat which may cause difficulty in swallowing and breathing; chest pain; stroke or fit/seizure; easy bruising; headache with jaw pain; pain behind ribs sometimes spreading to the neck and shoulders; nausea, vomiting or loss of appetite; rash, itchy, swollen, tender, blisters, dry and scaly, peeling and bleeding skin; altered pain sensation and altered skin colour; loss of hair; soreness or ulceration of the mouth; blurry/distorted vision; numbness and color changes in fingers and toes; disorientation or personality changes; unusual bleeding or bruising (including blood in your bowel motions/urine); yellowing of the skin or eyes; pain and inflammation at the injection site; painful urination, blood in the urine.

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™ Bleomycin Sulfate Injection

Active ingredient(s): Bleomycin Sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Bleomycin Sulfate 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 Bleomycin Sulfate Injection.**

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Bleomycin Sulfate Injection?

DBL Bleomycin Sulfate injection contains the active ingredient bleomycin sulfate. DBL Bleomycin Sulfate Injection is a type of medicine called an anti-neoplastic or cytotoxic agent. You may hear it referred to as chemotherapy. DBL Bleomycin Sulfate Injection works by blocking DNA production in cancer cells which weaken and destroy them. This medication can be used alone or in combination with another anti-cancer therapies.

DBL Bleomycin Sulfate Injection is used to treat cancer of the uterus cervix, penis, testes, immune system, lymphatic system, skin, oesophagus, head, neck and some lung cancers.

2. What should I know before treatment with DBL Bleomycin Sulfate Injection?

Warnings

You should not be given DBL Bleomycin Sulfate Injection if you have:

- An allergy or sensitivity to bleomycin sulfate.
- Severe lung problems or a lung infection
- You have previously received one course of medicine and show signs of reduced lung function or lung problems.

Check with your doctor if you:

- have lung problems with reduced lung function
- smoke or have smoked in the past
- have kidney problems
- have liver problems

- have had previous treatment for cancer
- have had or are having radiation therapy, especially to the chest
- have lymphatic problems
- have been exposed to an infection recently.

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.

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

Check with your doctor if you are pregnant or you (or your partner) intend to become pregnant.

DBL Bleomycin Sulfate Injection is potentially harmful to the fetus.

The use of DBL Bleomycin Sulfate injection should be avoided during pregnancy.

Both female and male patients must take effective measures to prevent pregnancy during treatment and following the end of the treatment with DBL Bleomycin Sulfate injection. Both female and male patients must consult with their healthcare provider about effective contraception options before, during and on finishing treatment with DBL Bleomycin Sulfate injection.

It is not known if DBL Bleomycin Sulfate injection may affect male and female fertility. Check with your doctor for advice on fertility preservation before you begin treatment.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if DBL Bleomycin Sulfate Injection passes into breast milk and is therefore not recommended while you are breast-feeding as there may be potential serious effects. It is recommended that women should discontinue breastfeeding prior to treatment with DBL Bleomycin Sulfate Injection.

Use in the elderly

There may be a greater chance of lung problems if you are over 70 years of age. Your doctor will monitor you closely for this.

3. What if I am taking other medicines?

Tell your doctor 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 may effect or be affected by DBL Bleomycin Sulfate Injection. These include:

- medicine used to treat heart failure e.g. digoxin
- medicine to prevent seizures/fits e.g. phenytoin
- other medicines to also treat cancer e.g. cisplatin
- other treatments for cancer e.g. radiation therapy or any other treatment which lowers your immune system
- general anaesthetics and/or oxygen therapy, which may be given to you during surgery
- medicines used to help fight infections e.g. granulocyte colony stimulating factor such as filgrastim.

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

4. How is DBL Bleomycin Sulfate Injection given?

How is DBL Bleomycin Sulfate Injection given

Your doctor will decide how you will receive the DBL Bleomycin Sulfate Injection and the length of time in which you should receive it. You could be given DBL Bleomycin Sulfate Injection in one of the following ways:

- an intravenous infusion (as a slow drip into a vein)
- an injection under the skin
- an injection into a muscle
- an injection into an artery, possibly in the chest

How much will be given

- Your doctor will decide how and how much DBL Bleomycin Sulfate Injection you will be given and how long you will be given it.
- DBL Bleomycin Sulfate Injection may be given alone or in combination with other medicines.
- The first time you are given DBL Bleomycin Sulfate Injection you may receive a small test dose to check for any allergic response to bleomycin sulfate before receiving the full dose.

If you are given too much DBL Bleomycin Sulfate Injection

Tell your doctor or nurse immediately if you are concerned that you may have been given too much DBL Bleomycin Sulfate Injection.

As DBL Bleomycin Sulfate Injection is given under the close supervision of your doctor it is very unlikely that you will receive too much. If you feel faint or experience dizziness, a fever, a rapid pulse, rapid shallow breathing, or cold clammy skin alert your doctor or nurse immediately as these may be signs of an overdose.

5. What should I know during treatment with DBL Bleomycin Sulfate Injection?

Things you should do

Keep follow up doctor's appointments and attend any tests as directed. Treatment with DBL Bleomycin Sulfate Injection requires your doctor to do some tests to check on your progress and detect any adverse effects such as tests for the kidneys and liver.

DBL Bleomycin Sulfate injection is known to affect the way the lungs work in some patients. These effects may be serious, therefore your doctor may arrange frequent tests such as chest X-rays to check how well your lungs are working while you are being treated. Tests may also be required after completion of treatment with DBL Bleomycin Sulfate Injection to check your lungs are not adversely affected.

During treatment with DBL Bleomycin Sulfate Injection you may be at increased risk of infection. Care should be taken to minimise cuts, impacts or exposure to infection.

Tell your doctor or nurse immediately if:

- you plan to have surgery that needs a general anaesthetic
- you are having radiation therapy
- you, or your partner, become pregnant while you are being treated with DBL Bleomycin Sulfate Injection.

During treatment with DBL Bleomycin Sulfate injection you may be at increased risk of lung changes. Your doctor may determine if the changes are medicine related and treatment needs to change.

Inform your doctor immediately if you experience:

- sudden cough, or lightheadedness or shortness of breath.
- chest pain
- fits/seizures
- allergic reaction with swelling of the face, lips, tongue or throat
- unusual bleeding or bruising
- yellowing of the skin or eyes
- painful urination with or without blood in the urine.

Remind any doctor, nurse, dentist, surgeon, anaesthetist, or pharmacist you visit that you are being treated with DBL Bleomycin Sulfate Injection.

Driving or using machines

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

Looking after your medicine

DBL Bleomycin Sulfate Injection will be stored appropriately at the hospital.

Getting rid of any unwanted medicine

The hospital staff will dispose of any leftover DBL Bleomycin Sulfate Injection.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

If you are over 70 years of age you may have an increased chance of experiencing side effects.

Side effects	What to do
- headaches with jaw pain - nausea, vomiting or loss of appetite - rash and other skin conditions such as dry and scaly skin, itchiness, swollen, tenderness, stretch marks, painful blisters, peeling and bleeding skin, altered pain sensation and altered skin colour - loss of hair - soreness or ulceration of the mouth - blurry/distorted vision - numbness and colour change in fingers and toes when exposed to the cold - disorientation or personality changes. - pain and inflammation at the injection site - painful urination with or without blood in the wee/urine - yellowing of the skin or eyes - tiredness	Speak to your doctor as soon as possible if you notice any of these side effects.
Side effects	What to do
- infection or pneumonia - rapid onset cough with shortness of breath which may quickly progress to severe respiratory distress - fever and chills - fatigue, dizziness - a dry, hacking cough (with or without phlegm) that may worsen with activity with fatigue - chest pain which may spread to the neck and shoulders - reduced lung capacity with difficulty breathing - allergic reaction with lightheadedness, wheezing or trouble breathing; or swelling of the face, lips, mouth, tongue or throat which may	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.

Side effects	What to do
- cause difficulty in swallowing or breathing - stroke or fit/seizure - pain behind the ribs, sometimes spreading to the neck and shoulders with fever - unusual bleeding or bruising (including blood in your poo/bowel motions or wee/urine)	

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

Some side effects (for example certain liver conditions, and blood abnormalities) can only be found when your doctor does tests to check your progress.

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them

After finishing it

The effects of bleomycin sulfate may take some time to occur and therefore any side effects may not occur until months after DBL Bleomycin Sulfate is administered. Even after you have finished receiving your DBL Bleomycin Sulfate treatment you should tell your doctor immediately if you notice any of the side effects listed above.

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/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.

DBL Bleomycin Sulfate Injection contains:

Active ingredient	bleomycin sulfate 15,000 IU
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There are no other ingredients.

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

What DBL Bleomycin Sulfate Injection looks like

DBL Bleomycin Sulfate injection is a cream to white coloured powder in a vial (AUST R 42569).

Who distributes DBL Bleomycin Sulfate Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in December 2025.