

BLENAMAX®

bleomycin sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BLENAMAX®. 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 taking BLENAMAX® 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 with the medicine. You may need to read it again.

What BLENAMAX is used for

BLENAMAX® is used to treat some types of cancers, and is also used to prevent or treat build-up of fluid around the lungs which can result from cancer. BLENAMAX® belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. BLENAMAX® is thought to work by stopping cancer cells from growing and multiplying. Your doctor may have prescribed BLENAMAX® for another reason. Ask your doctor if you have any questions about why BLENAMAX® has been prescribed for you.

BLENAMAX® may be used in combination with other medicines to treat cancer.

BLENAMAX® is not addictive.

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

BLENAMAX® is not recommended for use in children, as there is not enough information on its effects in children.

Before you use it

When you must not use it

Do not have BLENAMAX® if you have an allergy to bleomycin sulfate or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to BLENAMAX may include:

- shortness of breath
- wheezing
- difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash
- itching
- hives or flushed, red skin
- dizziness or light headedness
- back pain

Your doctor may give you a small test dose to see how you react to BLENAMAX®.

Do not have this medicine if you have previously had lung problems while receiving bleomycin.

If you are not sure whether you should start having BLENAMAX®, talk to your doctor or pharmacist.

Before you are given it

You must 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 if you have or have had any of the following health/medical conditions, especially the following:

- liver problems
- kidney problems
- lung problems, including asthma

Tell your doctor if you smoke.

There is a greater chance of bleomycin affecting your lungs if you smoke.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines used to treat cancer, BLENAMAX® is not recommended to be used during pregnancy. (If there is a need to consider it during your pregnancy, your doctor will discuss with you the benefits and risks of using it.)

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

It is recommended that you do not breast-feed while taking BLENAMAX®, as it may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you have not told your doctor about any of the above, tell them before you start having BLENAMAX®.

Taking other medicines

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

Some medicines and BLENAMAX® may interfere with each other. These include:

- phenytoin, a medicine used to treat epilepsy;
- digoxin, a medicine used to treat heart failure.

These medicines may be affected by BLENAMAX®, or may affect how well it works. You may need different amounts of your medicine, or you may need to have different medicines. Your doctor or pharmacist will advise you. Your doctor and pharmacist may have more information on medicines to be careful with or avoid while having BLENAMAX®.

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given. BLENAMAX® may be given alone or in combination with other drugs.

BLENAMAX® is given as a course or 'cycle'. You may receive a small test dose to check that you are not allergic. If no reaction occurs within 4-6 hours, the rest of the course will be given. A course may consist of a dose once or twice weekly, or it may be a cycle of a daily dose for 7 consecutive days. Several courses of BLENAMAX® 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 BLENAMAX® you receive.

How to take it

How it is given

BLENAMAX® must only be given by a doctor, nurse or other trained person.

BLENAMAX® is given as an injection either:

- under the skin
- into a vein
- into a muscle
- into an artery
- into the space around the lungs.

If you take too much (Overdose)

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

However, if you experience any side effects after being given BLENAMAX®, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

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

While you are using it

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 tests and other tests from time to time to check on your progress and detect any unwanted side effects.

In particular, your doctor will need to do checks on your lungs since BLENAMAX® is known to affect the way the lungs work in some people.

Keep follow up appointments with your doctor.

It is important to have your follow-up doses of BLENAMAX® 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 having BLENAMAX®.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are having BLENAMAX®.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are having BLENAMAX® or have received BLENAMAX® in the last 12 months.

If you become pregnant while having this medicine, tell your doctor.

BLENAMAX® 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 this medicine.

Things to be careful of

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

As with some other medicines, BLENAMAX® may cause tiredness in some people. Make sure you know how you react to BLENAMAX® before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired.

If this occurs do not drive.

If you drink alcohol, tiredness may be worse.

Side effects

During treatment with BLENAMAX®, you will require close medical supervision. It is important that you tell your doctor or nurse immediately if you have any problems, or if you do not feel well while you are having BLENAMAX®.

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

- feeling sick
- vomiting
- loss of appetite
- weight loss
- headache
- tiredness
- itching
- hives
- redness of the skin
- discolouration of skin and nails
- skin rash
- irritation, pain swelling or colouring of the skin around the needle during injection
- unusual hair loss or thinning

These are the more common side effects of BLENAMAX®.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- chills and fever
- mouth ulcers
- sore, red mouth
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- lack of white blood cells * frequent infections, fever, severe chills, sore throat or mouth ulcers

- bleeding or bruising more easily than normal
- tingling or numbness in hands or feet; pins and needles
- burning feeling when passing urine
- blood in the urine
- disorientation, behavioural changes
- bleeding from eye

These may be serious side effects. You may need medical attention. If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

Sudden Life-threatening Allergic Reaction-

- sudden signs of allergy such as rash, itching or hives on the skin
- swelling of the face, tongue or other parts of the body
- shortness of breath
- wheezing or trouble breathing
- swelling of the lungs causing coughing, difficulty breathing and wheezing

Heart Disease-

- fatigue
- chest pain
- palpitations
- altered heart beat
- stroke.

These are very serious side effects. You may need urgent medical attention or hospitalisation. Other side effects not listed above may occur in some patients.

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

The benefits and side effects of BLENAMAX® may take some time to occur.

Therefore even after you have finished your BLENAMAX® treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

After using it

If you are to have an operation at any time after you have received BLENAMAX®, tell your doctor that you have received this medicine.

Your doctor may need to take special measures to avoid the risk of lung problems.

Storage

BLENAMAX® must be stored at 2-8°C (Refrigerate. Do not freeze) and protected from light.

Product Description

What it looks like

BLENAMAX® is a cake of white powder in a glass vial. It must be dissolved in Water for Injection or 0.9% Sodium chloride solution before use. Each vial is used only once and any left over material is discarded.

Ingredients

Active ingredient:

bleomycin sulfate 15000 IU

Other ingredients:

- sodium hydroxide
- hydrochloric acid

BLENAMAX® does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

BLENAMAX is supplied in Australia by:
Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

AUST R Number: 76905

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