

BLEO 15 K

BLEO 15K Sulfate for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BLEO 15K for Injection. 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 taking BLEO 15K for Injection 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 BLEO 15K for Injection is used for

BLEO 15K belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may hear it referred to as chemotherapy medicine.

BLEO 15K is classified as an antitumour antibiotic. It interferes with the growth of cancer cells, which are eventually destroyed.

Your doctor may have prescribed BLEO 15K for another reason.

Ask your doctor if you have any questions about why BLEO 15K has been prescribed for you.

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

BLEO 15K is not recommended for use in children, as there have not

been enough studies of its effects in children.

Before you are given BLEO 15K

When you must not be given it

You must be given BLEO 15K for Injection if you have any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to BLEO 15K 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 BLEO 15K if you have any of the following conditions:

- low white blood cell (WBC) count
- 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 BLEO 15K, 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 BLEO 15K during pregnancy.

BLEO 15K may cause birth defects of 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 BLEO 15K and for at least 12 weeks after stopping. Your doctor will discuss this with you.

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

Like most antineoplastic medicines, BLEO 15K is not recommended while you are breastfeeding.

Tell your doctor or pharmacist if you 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 BLEO 15K affecting your lungs if you smoke.

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

There is a greater chance of BLEO 15K affecting your lungs if you have had radiation therapy, especially to the chest.

If you have been told by your doctor or pharmacist about any

of the above, tell them before you start treatment with BLEO 15K.

Taking other medicines

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

Some medicines may interfere with BLEO 15K. These include:-

- *digoxin, a medicine used to treat heart failure*
- *phenytoin, a medicine used to treat epilepsy, fits and 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*
- *any medicine which suppresses your immune system eg azathioprine*
- *general anaesthetics*
- *granulocyte colony stimulating factor (such as filgrastim and lenograstim).*

These medicines may be affected by BLEO 15K, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Some of these medicines and BLEO 15K may interfere with each other even if they are not given at the same time. Your doctor or pharmacist will advise you.

Do not have any vaccinations (immunisations) without your doctor's approval while you are being treated with BLEO 15K, and for about one month after you stop treatment with it.

BLEO 15K may lower your body's resistance to infection and there is a chance that you may get the infection the immunisation is meant to prevent. In addition, other people close to 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 of medicines to be careful with or avoid while you are being given the BLEO 15K.

How BLEO 15K is given

How much is given

Your doctor will decide what dose of BLEO 15K 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.

BLEO 15K may be given alone or in combination with other drugs.

Several courses of BLEO 15K 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 BLEO 15K you receive.

How it is given

BLEO 15K should only be given by a doctor or nurse.

BLEO 15K 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 BLEO 15K, you will normally receive a small test dose to check that you are not allergic to BLEO 15K. If no reaction occurs, the full dose will be given.

How long it is given

A course of BLEO 15K 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 BLEO 15K 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 tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

You may need urgent medical attention.

Symptoms of a BLEO 15K overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

While you are using BLEO 15K for Injection

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of BLEO 15K.

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 BLEO 15K 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 BLEO 15K.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given BLEO 15K.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given BLEO 15K.

If you become pregnant while you are being treated with BLEO 15K, tell your doctor immediately.

BLEO 15K 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 cutter.
- Avoid contact sports or other situations where bruising or injury may occur.

While you are being given BLEO 15K

Your doctor should order regularly tests to check the number of blood cells in your blood. The results of these tests will be used to determine the amount of BLEO 15K you will be given for your next dose.

While you are being given BLEO 15K your doctor should order

regular tests to check how well your kidneys are working.

Your doctors should also order periodic tests to estimate how well your liver is working during treatment with BLEO 15K.

BLEO 15K 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 BLEO 15K. These should continue for up to 4 weeks after completion of treatment with BLEO 15K.

BLEO 15K and its 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.

- Flush the toilet twice to dispose of any body fluids and waste.
- Wear 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 spills. 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 BLEO 15K affects you.

As with some other medicines, BLEO 15K may cause dizziness, light-headedness and tiredness in some people. Make sure you know how you react to BLEO 15K 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 give BLEO 15K.

Like other medicines that treat cancer, BLEO 15K 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 more common side effects of BLEO 15K.

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 allergic reactions 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 of the scalp is a less common side effect of BLEO 15K and occurs in a small number of patients. The severity of hair loss will depend on the dose of BLEO 15K given. It is more common when other anti-cancer medicines are used together with BLEO 15K.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you feel unwell.

Do not be alarmed by this list of possible side effects

You may not experience any of them.

The effects of BLEO 15K 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 BLEO 15K is given.

Therefore, even after you have finished receiving your treatment you should tell your doctor immediately if you notice any of the side effects listed above.

After you have been given BLEO 15K for Injection

Storage

BLEO 15K for Injection 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 at between 2 - 8°C. (Refrigerate. Do not freeze).

Product description

What it looks like

BLEO 15K for Injection is an off white cake. It must be dissolved in Water for Injections, 0.9% Sodium Chloride solution or Bacteriostatic water for Injection before use.

Ingredients

Active ingredients:

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

There are no other ingredients.

BLEO 15K for Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

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