

# CIPLA BLEOMYCIN 15K

## 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 using CIPLA BLEOMYCIN 15K?

CIPLA BLEOMYCIN 15K contains the active ingredient bleomycin. CIPLA BLEOMYCIN 15K is used to interfere with the growth of cancer cells, which are eventually destroyed

For more information, see Section [1. Why am I using CIPLA BLEOMYCIN 15K?](#) in the full CMI.

### 2. What should I know before I use CIPLA BLEOMYCIN 15K?

Do not use if you have ever had an allergic reaction to CIPLA BLEOMYCIN 15K or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use CIPLA BLEOMYCIN 15K?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with CIPLA BLEOMYCIN 15K and affect how it works.

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

### 4. How do I use CIPLA BLEOMYCIN 15K?

- Your doctor will decide what dose of CIPLA BLEOMYCIN 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.
- CIPLA BLEOMYCIN 15K may be given alone or in combination with other drugs.

More instructions can be found in Section [4. How do I use CIPLA BLEOMYCIN 15K?](#) in the full CMI.

### 5. What should I know while using CIPLA BLEOMYCIN 15K?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist or nurse you visit that you are using CIPLA BLEOMYCIN 15K.</li><li>If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given CIPLA BLEOMYCIN 15K.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.</li><li>Avoid contact sports or other situations where bruising or injury may occur.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how CIPLA BLEOMYCIN 15K affects you</li><li>May cause dizziness, light-headedness and tiredness in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>If you drink alcohol, dizziness or light-headedness may be worse</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep in a cool dry place, protected from light, where the temperature stays at between 2 - 8°C. (Refrigerate. Do not freeze).</li></ul>

For more information, see Section [5. What should I know while using CIPLA BLEOMYCIN 15K?](#) in the full CMI.

### 6. Are there any side effects?

You may experience common side effects like- nausea, vomiting, headache, pain and inflammation at the injection site, serious side effects-fever, chills, chest pain, shortness of breath, blurred vision or eye pain.

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.

# CIPLA BLEOMYCIN 15K

Active ingredient(s): *Bleomycin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using CIPLA BLEOMYCIN 15K. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CIPLA BLEOMYCIN 15K.**

Where to find information in this leaflet:

- [1. Why am I using CIPLA BLEOMYCIN 15K?](#)
- [2. What should I know before I use CIPLA BLEOMYCIN 15K?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use CIPLA BLEOMYCIN 15K?](#)
- [5. What should I know while using CIPLA BLEOMYCIN 15K?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using CIPLA BLEOMYCIN 15K?

CIPLA BLEOMYCIN 15K contains the active ingredient **bleomycin**. CIPLA BLEOMYCIN 15K is classified as an anti-tumour antibiotic. CIPLA BLEOMYCIN 15K belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may hear it referred to as chemotherapy medicine.

**CIPLA BLEOMYCIN 15K is used to interfere with the growth of cancer cells, which are eventually destroyed.**

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

CIPLA BLEOMYCIN 15K is not recommended for use in children, as there have not been enough studies of its effects in children.

## 2. What should I know before I use CIPLA BLEOMYCIN 15K?

### Warnings

**Do not use CIPLA BLEOMYCIN 15K if:**

- you are allergic to bleomycin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have problems with blood clotting
- you have severe lung problems, a lung infection or reduced lung function.

Symptoms of an allergic reaction to CIPLA BLEOMYCIN 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

**Check with 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.
- are not sure whether you should start treatment with CIPLA BLEOMYCIN 15K
- have kidney disease, liver disease, lung disease
- are a smoker. There is a greater chance of CIPLA BLEOMYCIN 15K affecting your lungs if you smoke.
- have had radiation therapy for cancer. There is a greater chance of CIPLA BLEOMYCIN 15K affecting your lungs if you have had radiation therapy, especially to the chest.

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 and breastfeeding

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of treatment with CIPLA BLEOMYCIN 15K during pregnancy.

CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 15K and for at least 12 weeks after stopping. Your doctor will discuss this with you.

Like most antineoplastic medicines, CIPLA BLEOMYCIN 15K is not recommended while you are breast-feeding.

## 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 interfere with CIPLA BLEOMYCIN 15K and affect how it works.**

- 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 CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 15K 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 the CIPLA BLEOMYCIN 15K.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CIPLA BLEOMYCIN 15K.**

#### 4. How do I use CIPLA BLEOMYCIN 15K?

##### How much to take

- Your doctor will decide what dose of CIPLA BLEOMYCIN 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.
- CIPLA BLEOMYCIN 15K may be given alone or in combination with other drugs.
- Several courses of CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 15K you receive.

##### How to take

- *CIPLA BLEOMYCIN 15K should only be given by a doctor or nurse.*
- ***CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 15K, you will normally receive a small test dose to check that you are not allergic to CIPLA BLEOMYCIN 15K. If no reaction occurs, the full dose will be given.

##### How long is it given

A course of CIPLA BLEOMYCIN 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.

##### If you use too much CIPLA BLEOMYCIN 15K

If you think that you have used too much CIPLA BLEOMYCIN 15K, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

##### You should do this even if there are no signs of discomfort or poisoning.

As CIPLA BLEOMYCIN 15K will be given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

#### 5. What should I know while using CIPLA BLEOMYCIN 15K?

##### Things you should do

##### Call your doctor straight away if you:

- plan to have surgery that needs a general anaesthetic,
- are about to be started on any new medicine
- If you become pregnant while you are being treated

Remind any doctor, dentist or pharmacist or nurse you visit that you are using CIPLA BLEOMYCIN 15K

##### 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 CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 15K.

CIPLA BLEOMYCIN 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 cutters.
- Avoid contact sports or other situations where bruising or injury may occur.

### While you are being given CIPLA BLEOMYCIN 15K

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 CIPLA BLEOMYCIN 15K you will be given for your next dose.

While you are being given CIPLA BLEOMYCIN 15K 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 CIPLA BLEOMYCIN 15K.

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how CIPLA BLEOMYCIN 15K affects you.**

CIPLA BLEOMYCIN 15K may cause dizziness in some people. May also cause light-headedness and tiredness. Make sure you know how you react to CIPLA BLEOMYCIN 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.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol may cause dizziness or light-headedness which may be worse.

### Looking after your medicine

- CIPLA BLEOMYCIN 15K for Injection will be stored in the pharmacy or on the ward.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.
- Store where the temperature stays at between 2 - 8°C. (Refrigerate. Do not freeze).

**Keep it where young children cannot reach it.**

## 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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Nausea, vomiting or loss of appetite</li> <li>• Tiredness or weakness</li> <li>• Headaches</li> <li>• Pain and inflammation at the injection site</li> <li>• Rash and other skin conditions such as itchiness, tenderness, altered pain sensation and altered skin colour</li> <li>• Conjunctivitis (infection/inflammation of the eye)</li> <li>• Soreness or ulceration of the mouth.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Cough and shortness of breath</li> <li>• Fever and chills</li> <li>• Signs of allergic reactions</li> <li>• Disorientation or personality changes</li> <li>• Severe nausea and vomiting</li> <li>• Severe abdominal pain</li> <li>• Chest pain</li> <li>• Severe headache</li> <li>• Severe mouth ulceration and/or</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious</b></p>

anal ulceration <ul style="list-style-type: none"> <li>• Unusual bleeding or bruising (including blood in your stools or urine)</li> <li>• Painful or difficult urination</li> <li>• Blurred vision or eye pain</li> <li>• Yellowing of the skin or eyes</li> <li>• Fits (seizures)</li> </ul>	<b>side effects.</b>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

The effects of CIPLA BLEOMYCIN 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 CIPLA BLEOMYCIN 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.

**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](http://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.

**What CIPLA BLEOMYCIN 15K contains**

<b>Active ingredient (main ingredient)</b>	Bleomycin Sulfate 15,000IU (15 units USP) per vial
<b>Other ingredients (inactive ingredients)</b>	No other ingredients

**Do not take this medicine if you are allergic to any of these ingredients.**

**What CIPLA BLEOMYCIN 15K looks like**

CIPLA BLEOMYCIN 15K is sterile freeze-dried white to off white powder. It must be dissolved in Water for Injections, 0.9% Sodium Chloride solution or Bacteriostatic water for Injection before use. (AUST R 220440)

CIPLA BLEOMYCIN 15K glass vials are available in packs sizes of 1's and 10's.

**Who distributes CIPLA BLEOMYCIN 15K**

Cipla Australia Pty Ltd  
 Level 1, 132 – 136 Albert Rd,  
 South Melbourne VIC 3205  
 drugsafety@cipla.com  
 Toll Free number: 1800 569 074

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