

Consumer Medicine Information**What is in this leaflet**

This leaflet answers some common questions about BiCNU®. 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 BiCNU against the benefits that are expected. This leaflet does not contain everything about BiCNU. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What BiCNU is used for

BiCNU is used to treat malignant glioma, a type of brain cancer, and multiple myeloma, a cancer of the blood. It may also be used to treat other types of cancers called Hodgkin's Disease and Non-Hodgkin's Lymphomas.

BiCNU belongs to a group of medicines called cytotoxic medicines. You may also hear of these being called chemotherapy medicines. BiCNU may be used in combination with other medicines to treat your cancer.

Your doctor may have prescribed BiCNU for another use. Ask your doctor if you have any questions about why BiCNU was prescribed for you. This medicine is available only with a doctor's prescription.

How BiCNU works

BiCNU works by killing cancer cells. The use of BiCNU to treat your condition can lead to side-effects, which are discussed below.

Before you are given BiCNU**When you must not be given it**

You must not have BiCNU if you have a history of severe allergic reactions to BiCNU or to any of the ingredients listed at the end of this leaflet.

Do not have BiCNU if you have, or have had, any of the following medical conditions, unless you have discussed it with your doctor:

- kidney problems
- lung disease
- blood disorder with a reduced number of white blood cells
- blood disorder with a low blood platelet count
- blood disorder with a decreased number of red blood cells
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer

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.

Females: tell your doctor if you are pregnant or intend to become pregnant. Like most cytotoxic medicines, BiCNU is not recommended for use during pregnancy. If

there is any need to consider BiCNU during your pregnancy, your doctor will discuss with you the benefits and risks of using it. BiCNU may affect your developing baby if you take it during pregnancy.

Males: tell your doctor if your partner intends to become pregnant while you are using BiCNU or shortly after you have stopped using BiCNU.

You should use some kind of birth control while you are using BiCNU and for at least 12 weeks after you stop using it. BiCNU may cause birth defects if either the male or female is using it at the time of conception.

Do not breastfeed while using BiCNU. It is not known whether BiCNU passes into breast milk. Therefore there is a possibility that the breast-fed baby may be affected.

If you are not sure whether you should start having BiCNU, talk to your doctor.

Before you are given it

Tell your doctor 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 medical conditions, especially the following:

- liver problems
- kidney problems
- heart problems, including a heart attack
- lung problems, including asthma
- blood disorder with a reduced number of red or white blood cells
- If you are pregnant or intend to become pregnant.
- If you are breast-feeding or intend to breast-feed.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and BiCNU may interfere with each other. These medicines may be affected by BiCNU, 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 will advise you.

BiCNU when used in combination with other medicines or radiation therapy may further depress your immune system.

Your doctor may have more information on medicines to be careful with or avoid while having BiCNU.

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

While you are receiving BiCNU**Things you must do:**

- Tell your doctor immediately if you become pregnant while taking BiCNU.
- Tell all of the doctors, dentists and pharmacists who are treating you that you are taking BiCNU.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking BiCNU.

- 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 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 BiCNU at the appropriate times to get the best effects from your treatments. If you forget a hospital appointment immediately contact your doctor.

BiCNU 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 who have 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, toothpick or dental floss. 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.
- 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 you may bruise or get injured.

Things you must not do:

- Do not drink alcohol while taking BiCNU. You may feel flushed or get headaches.

Things to be careful of:

- As with other anticancer medicines, BiCNU may cause nausea, dizziness or tiredness in some people. Make sure you know how you react to BiCNU before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or tired. If this occurs do not drive. If you drink alcohol, dizziness or tiredness may be worse.

How BiCNU is given

Your doctor will decide what dose of BiCNU you will receive based in the characteristics of your cancer. The dose also depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given. BiCNU may be given alone or in combination with other drugs.

BiCNU is administered as a slow infusion into your vein, over 1 to 2 hours. The infusion will be prepared and given in hospital by your doctor or nurse.

How long is BiCNU given

BiCNU is usually given every six weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

Several courses of BiCNU 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 BiCNU you receive.

Overdose

As BiCNU 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 BiCNU, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving BiCNU.

Like all medicines, it is possible that BiCNU may have unwanted side effects in some people. During treatment with BiCNU you will require close medical supervision.

The more common side effects of BiCNU are:

- Suppression of your immune system; reduced white blood cells, reduced platelets, reduced red blood cells
- Nausea, vomiting
- Lung toxicity
- Respiratory disorders (lung related disorders) with breathing problems

Tell your doctor or nurse immediately or if you are not currently in hospital, go to accident and emergency at your nearest hospital if you notice any of the following:

- Symptoms of an allergic reaction, such as:
 - 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
- Frequent infections, fever, severe chills, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal
- Passing little or no urine, drowsiness, nausea, vomiting and breathlessness
- Weakness, tiredness, loss of appetite, weight loss and stomach pain
- Changes to vision or loss of sight
- Shortness of breath, particularly with exertion, chronic dry, hacking coughing
- Chest discomfort, irregular heartbeat
- Loss of appetite and rapid weight loss
- Pain, swelling or burning at the injection site

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Product Description

BiCNU is a pale yellow powder. Each BiCNU 100mg amber vial comes with a clear ampoule containing the ethanol required for the preparation of the infusion.

Active ingredient: carmustine

Other ingredient: ethanol (required for preparation of the infusion)

Storage

BiCNU will be stored in the pharmacy or on the hospital ward. The unopened vials of the dry powder will be stored under refrigeration.

Sponsored by

Emcure Pharmaceuticals Pty Ltd
Shop 3, 26 Henley Road,
Homebush West,
NSW-2140 Australia

Registration Numbers

BiCNU - Each carton contains a vial containing 100 mg carmustine and a clear glass vial containing 3 mL ethanol - AUST R 19243.

Where to get further information

Your doctor is the best person to answer any further questions you may have about BiCNU. Anything your doctor tells you about BiCNU should be followed even if it is different from what is in this leaflet.

Date of Preparation: 02/05/2017

AU_CMI_BiCNU_V7.0_May. / 2017