

RIBOMUSTIN®

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 RIBOMUSTIN?

RIBOMUSTIN contains the active ingredient bendamustine hydrochloride. RIBOMUSTIN is used to treat certain types of cancer.

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

2. What should I know before I use RIBOMUSTIN?

Do not use if you have ever had an allergic reaction to RIBOMUSTIN or any of the ingredients listed at the end of the CMI. Do not use this product if you are pregnant or breastfeeding. Do not use RIBOMUSTIN if you have liver problems, bone marrow problems, had recent major surgeries, or an active infection.

Talk to your doctor if you have any other medical conditions, take any other medicines.

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

3. What if I am taking other medicines?

Some medicines may interfere with RIBOMUSTIN 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 RIBOMUSTIN is given?

- Your treatment with RIBOMUSTIN will take place in a specialised medical unit, under the supervision of a doctor experienced in the use of medicines that treat cancer.
- RIBOMUSTIN is administered into a vein over 30-60 minutes in various dosages, either alone (monotherapy) or in combination with other medicines.

More instructions can be found in Section [4. How RIBOMUSTIN is given?](#) in the full CMI.

5. What should I know while using RIBOMUSTIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RIBOMUSTIN.
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	<ul style="list-style-type: none"> • Keep all of your doctor's appointments so that your progress can be checked. • Keep follow-up appointments with your doctor. It is important to have your follow-up doses of RIBOMUSTIN at the appropriate times to get the best effects from your treatment. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. • RIBOMUSTIN 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. Therefore, you should take certain precautions to reduce your risk of infection or bleeding.
Driving or using machines	<ul style="list-style-type: none"> • Do not drive or use machines until you know how RIBOMUSTIN affects you. If you feel

	light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
Looking after your medicine	<ul style="list-style-type: none"> • RIBOMUSTIN should be kept below 25°C, protected from light. It should be stored in a cool, dry place e.g. do not store in the bathroom. Keep out of reach of children.

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

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). Some of the common serious side effects include fever with low counts of white blood cells and lung infection. Some side effects may require urgent medical attention.

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.

RIBOMUSTIN®

Active ingredient(s): Bendamustine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using RIBOMUSTIN. **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 RIBOMUSTIN.**

Where to find information in this leaflet:

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

1. Why am I using RIBOMUSTIN?

RIBOMUSTIN contains the active ingredient bendamustine hydrochloride. RIBOMUSTIN belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. These medicines are used to kill cancer cells.

RIBOMUSTIN is used for the treatment of certain types of cancer.

RIBOMUSTIN is used alone (monotherapy) or in combination with other medicines for the treatment of the following forms of cancer:

- Chronic lymphocytic leukaemia;
- Indolent, Stage III-IV Non-Hodgkin's Lymphoma and Stage III-IV Mantle Cell Lymphoma. It is prescribed for patients who have not been previously treated.
- Indolent Non-Hodgkins Lymphoma. It is prescribed for patients who have received one or more prior treatment and whose cancer is still progressing.

2. What should I know before I use RIBOMUSTIN?

Warnings

Do not use RIBOMUSTIN if:

- you are allergic to bendamustine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Are breastfeeding.
- Have severe liver dysfunction (damage to the functional cells of the liver);
- Have yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice);

- Have severely disturbed bone marrow function (bone marrow depression) and serious changes in your number of white blood cells and platelets in the blood;
- Have had major surgical operations less than 30 days before starting treatment;
- Have an infection, especially one accompanied by a reduction in white blood cells (leukocytopenia);
- In combination with yellow fever vaccines.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - reduced capability of the bone marrow to replace blood cells
 - infections, including fever or lung symptoms
 - skin reaction. The reaction may increase in severity
 - heart disease (e.g. heart attack, chest pain, severely disturbed heart rhythms)
 - hepatitis B infection
 - severe allergic or hypersensitivity reactions. You should pay attention to infusion reactions after your first cycle of RIBOMUSTIN therapy.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use this medicine if you are pregnant.

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

Like most medicines used to treat cancer, RIBOMUSTIN is not recommended for use during pregnancy.

Women of childbearing potential must use effective methods of contraception both before and during RIBOMUSTIN therapy. Men receiving treatment with RIBOMUSTIN are advised not to conceive a child during treatment for up to 6 months afterwards. Before starting treatment, you should seek advice on storing sperm because of the possibility of permanent infertility.

Do not breast-feed if you are using this medicine.

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

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 RIBOMUSTIN and affect how it works.

In particular, tell your doctor if you are taking any of the following:

- medicines that may result in excessive immunosuppression, such as cyclosporine or tacrolimus.
- fluvoxamine, medicines used to treat depression.
- ciprofloxacin and aciclovir, medicines used to treat infections.
- cimetidine, a medicine used to treat duodenal, gastric ulcers.
- viral vaccination.
- medicines that inhibit the formation of blood in the bone marrow.

These medicines may be affected by RIBOMUSTIN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RIBOMUSTIN.

4. How RIBOMUSTIN is given?

Your treatment with RIBOMUSTIN will take place in a specialised medical unit, under the supervision of a doctor experienced in the use of medicines that treat cancer.

Treatment should not be started if your white blood cells (leukocytes) have fallen to counts below 3,000 cells/ μ L and/or your blood platelets have fallen to counts below 75,000 cells/ μ L. Your doctor will determine these values at regular intervals.

How much is given

- Your doctor will decide what dose you will receive. The dose will be calculated from your height and weight. It will also depend on factors such as kidney function, liver function and other medicines you are being given.
- Dose for Chronic Lymphocytic Leukaemia:
 - 100mg per square metre of your body surface area
 - Cycle should be repeated after 4 weeks up to 6 times.
- Dose for progressing Non-Hodgkin's Lymphoma:
 - 120mg per square metre of your body surface area on days 1 and 2
 - Cycle should be repeated after 3 weeks up to 6 times
- Dose for previously untreated indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma:
 - 90mg per square metre on days 1 and 2
 - Cycle should be repeated after 4 weeks up to 6 cycles.
 - Your doctor may change the dose during treatment depending on your response.
 - Ask your doctor if you want to know more about the dose of RIBOMUSTIN you receive.

How RIBOMUSTIN is given

- RIBOMUSTIN will be dissolved in sterile normal sodium chloride (salt) solution for injection.

- RIBOMUSTIN is administered into a vein over 30-60 minutes in various dosages, either alone (monotherapy) or in combination with other medicines.

Unintentional injection into the tissue outside blood vessels (extravasal injection) should be stopped immediately. The needle should be removed after a short aspiration. Thereafter, the affected area of tissue should be cooled. The arm should be elevated. Additional treatments like the use of corticosteroids are not of clear benefit.

How long is RIBOMUSTIN given

- There is no time limit laid down as a general rule for treatment with RIBOMUSTIN. Duration of treatment depends on disease and response to treatment.

If you are given too much RIBOMUSTIN

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

However, if you experience side effects after being given RIBOMUSTIN, you may need urgent medical attention.

You should immediately:

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

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

5. What should I know while using RIBOMUSTIN?

Things you should do

- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some blood, urine or other tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- **Keep follow-up appointments with your doctor.** It is important to have your follow-up doses of RIBOMUSTIN at the appropriate times to get the best effects from your treatment.
- **Tell any other doctors, dentists and pharmacists who are treating you that you are using RIBOMUSTIN.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.
- **If you become pregnant or your partner becomes pregnant while being given RIBOMUSTIN, tell your doctor immediately.**

Decrease in blood cells

RIBOMUSTIN 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.
- 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 cutter.

Driving or using machines

Do not drive or use any machines or tools until you know how RIBOMUSTIN affects you.

This medicine may cause sleepiness, dizziness, lack of coordination or fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Looking after your medicine

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

- RIBOMUSTIN should be kept below 25°C, protected from light.

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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

RIBOMUSTIN will be disposed of appropriately by the healthcare professionals.

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"> • Low counts of white blood cells; decrease in the red pigment of the blood (haemoglobin); low counts platelets; decreased number of red blood cells (anaemia) • Infections • Feeling sick (nausea); vomiting; fatigue; chills, fever, headache or cough • Mucosal inflammation • Increased blood level of creatinine, glucose or urea • Bleeding • Hypersensitivity reactions such as allergic inflammation of the skin (dermatitis), nettle rash (urticaria) • A rise in liver enzymes AST/ALT • A rise in bile pigment 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • A rise in the enzyme alkaline phosphatase • Low potassium, sodium or calcium blood levels • Disturbed function of the heart; disturbed heart rhythms (arrhythmia) • Low or high blood pressure • Diarrhoea; constipation, or stomach pain • Sore mouth • Loss of appetite or weight loss • Hair loss • Missed periods (amenorrhoea) • Insomnia, anxiety, or depression • Dehydration including excessive thirst and urine production 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Infection of the blood (sepsis) • Severe allergic hypersensitivity reactions (anaphylactic reactions); signs similar to anaphylactic reactions (anaphylactoid reactions) • Drowsiness • Loss of voice (aphonia) • Acute circulatory collapse • Reddening of the skin (erythema); inflammation of the skin (dermatitis); itching; skin rash • Excessive sweating 	<p>Tell your doctor as soon as possible if you notice any of these serious side effects.</p>
<ul style="list-style-type: none"> • Pneumonia (primary atypical inflammation of the lungs) • Break-down of red blood cell • Anaphylactic shock (rapid decrease in blood 	<p>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.</p>

Serious side effects	What to do
<p>pressure sometimes with skin reactions rash)</p> <ul style="list-style-type: none"> • Disturbed sense of taste; altered sensations • Feeling unwell; pain in the limbs • Anticholinergic syndrome (disease of the nervous system); neurological disorders • Ataxia (lack of coordination) • Inflammation of the brain; inflammation of the veins • Increased heart rate; heart attack; chest pain; heart failure • Formation of tissue in the lungs (fibrosis of the lungs) • Bleeding inflammation of the gullet; bleeding stomach • Infertility • Multiple organ failure 	

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.

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.

What RIBOMUSTIN contains

Active ingredient (main ingredient)	Bendamustine hydrochloride
Other ingredients (inactive ingredients)	Mannitol

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

What RIBOMUSTIN looks like

RIBOMUSTIN is a white, microcrystalline powder in a brown glass vial with rubber stopper and an aluminium flip-off cap.

Each pack contains one single-use vial:

- RIBOMUSTIN 25mg vial (AUST R 211685)
- RIBOMUSTIN 100mg vial (AUST R 211684)

Who distributes RIBOMUSTIN

JANSSEN-CILAG PTY LTD

1-5 Khartoum Rd

Macquarie Park NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

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