

RIBOMUSTIN®

Bendamustine Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RIBOMUSTIN powder for injection. 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 being given RIBOMUSTIN 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 while being treated.

You may need to read it again.

What RIBOMUSTIN is used for

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you are given RIBOMUSTIN

When you must not use it

Do not use RIBOMUSTIN if you:

- Are hypersensitive (allergic) to the active substance, bendamustine hydrochloride or any of the other ingredients listed at the end of this leaflet;
- 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.

Some of the symptoms of an allergic reaction 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

Do not use this medicine if you are pregnant.

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

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

Before you start to use it

Tell 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.

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.

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.

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

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking RIBOMUSTIN.

Taking other medicines

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

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.
- flvoxamine, 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 cytotoxic medicinal products.

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 not treated 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 it 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.

How long it is 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.

What do I do if I receive too much? (overdose)

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

While you are using RIBOMUSTIN

Things you must 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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RIBOMUSTIN.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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 while taking this medicine, tell your doctor immediately. 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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Like all medicines, RIBOMUSTIN can have side effects. Some of these effects may be serious. However, there may be ways to reduce the discomfort of these effects. You may need medical treatment if you get some of the side effects.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with RIBOMUSTIN.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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
- 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

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

- 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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Pneumonia (primary atypical inflammation of the lungs)
- Break-down of red blood cell
- Anaphylactic shock (rapid decrease in blood pressure sometimes with skin reactions rash)
- 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 that is making you feel unwell.

After using RIBOMUSTIN

Storage

RIBOMUSTIN should be kept in a cool dry place, protected from light, where temperature stays below 25°C.

Product Description

What it 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.

Ingredients

Active ingredient:

- Bendamustine hydrochloride 25mg
- Bendamustine hydrochloride 100mg

Other ingredients: mannitol.

Sponsor

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Registration Numbers

RIBOMUSTIN 25mg vial: AUST R 211685
RIBOMUSTIN 100mg vial: AUST R 211684

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