

BENDAMUSTINE VIATRIS

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 being given BENDAMUSTINE VIATRIS?

BENDAMUSTINE VIATRIS contains the active ingredient bendamustine hydrochloride. BENDAMUSTINE VIATRIS is used for the treatment of certain types of cancer. For more information, see Section [1. Why am I being given BENDAMUSTINE VIATRIS?](#) in the full CMI.

2. What should I know before I am given BENDAMUSTINE VIATRIS?

Do not use if you have ever had an allergic reaction to bendamustine hydrochloride 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 am given BENDAMUSTINE VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BENDAMUSTINE VIATRIS 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 is BENDAMUSTINE VIATRIS given?

- Your treatment with BENDAMUSTINE VIATRIS will take place in a specialised medical unit, under the supervision of a doctor experienced in the use of cytotoxic medicinal products.
- 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.

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

5. What should I know while I am given BENDAMUSTINE VIATRIS?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are using BENDAMUSTINE VIATRIS. • Keep all of your doctor’s appointments and keep follow-up appointments with your doctor to check your progress. • Avoid people with infections. • Be careful when using a toothbrush, toothpick or dental floss. • Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutter
Driving or using machines	• Be careful driving or operating machinery until you know how BENDAMUSTINE VIATRIS affects you. • This medicine may cause sleepiness, dizziness, lack of coordination or fatigue in some people.
Looking after your medicine	• Store in a cool dry place, protected from light, where temperature stays below 25°C

For more information, see Section [5. What should I know while I am given BENDAMUSTINE VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: infections, feeling sick (nausea), vomiting, fatigue, chills, fever, headache or cough, bleeding, hypersensitivity reactions such as allergic inflammation of the skin, diarrhoea, constipation, stomach pain, sore mouth, loss of appetite, hair loss, missed periods, insomnia, anxiety, or depression, dehydration. **Serious side effects:** drowsiness, severe allergic hypersensitivity reactions, inflammation or reddening of the skin, loss of voice, excessive sweating, anaphylactic shock, disturbed sense of taste, altered sensations, lack of coordination, chest pain. **This is not a complete list of side effects.**

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.

BENDAMUSTINE VIATRIS

Active ingredient(s): bendamustine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using BENDAMUSTINE VIATRIS. **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 BENDAMUSTINE VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I being given BENDAMUSTINE VIATRIS?

BENDAMUSTINE VIATRIS contains the active ingredient bendamustine hydrochloride. BENDAMUSTINE VIATRIS 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.

BENDAMUSTINE VIATRIS is used for the treatment of certain types of cancer.

BENDAMUSTINE VIATRIS 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.

2. What should I know before I am given BENDAMUSTINE VIATRIS?

Warnings

Do not use BENDAMUSTINE VIATRIS if you:

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

Some of the symptoms of an allergic reaction may include:

- o shortness of breath
- o wheezing or difficulty breathing
- o swelling of the face, lips, tongue or other parts of the body
- o rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

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

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.

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

Do not use this medicine if you are pregnant or intend to become pregnant.

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

Do not use this medicine if you are breastfeeding or intend to breastfeed.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

Fertility

Women of childbearing potential must use effective methods of contraception both before and during BENDAMUSTINE VIATRIS therapy. Men receiving treatment with BENDAMUSTINE VIATRIS 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.

If you have not told your doctor about any of the above, tell them before you start taking BENDAMUSTINE VIATRIS.

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 BENDAMUSTINE VIATRIS 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 BENDAMUSTINE VIATRIS 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.

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

4. How is BENDAMUSTINE VIATRIS given?

Your treatment with BENDAMUSTINE VIATRIS 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:
 - o 100 mg per square metre of your body surface area
 - o Cycle should be repeated after 4 weeks up to 6 times.
- Dose for progressing Non-Hodgkin's Lymphoma:
 - o 120 mg per square metre of your body surface area on days 1 and 2
 - o 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:
 - o 90 mg per square metre on days 1 and 2
 - o 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 BENDAMUSTINE VIATRIS you receive.

How is it given

BENDAMUSTINE VIATRIS will be dissolved in sterile normal sodium chloride (salt) solution for injection.

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

How long is it given

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

If I receive too much BENDAMUSTINE VIATRIS

As BENDAMUSTINE VIATRIS 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 BENDAMUSTINE VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, 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 I am being given BENDAMUSTINE VIATRIS?

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 BENDAMUSTINE VIATRIS 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 BENDAMUSTINE VIATRIS.
- 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.
- **BENDAMUSTINE VIATRIS 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:**
 - o 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.
 - o 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.
 - o Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutter.

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Things to be careful of

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BENDAMUSTINE VIATRIS affects you.

BENDAMUSTINE VIATRIS 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.

Looking after your medicine

- Store below 25°C.

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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
• 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	Speak to your doctor if you have any of these less serious side effects.

Less serious side effects	What to do
• 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
• 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	Call your doctor straight away, if you notice any of these serious side effects.
• 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	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.

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 BENDAMUSTINE VIATRIS contains

Active ingredient (main ingredient)	bendamustine hydrochloride
Other ingredients (inactive ingredients)	mannitol

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

What BENDAMUSTINE VIATRIS looks like

BENDAMUSTINE VIATRIS is a white to off-white lyophilised powder in a glass vial with rubber stopper and an aluminium flip-off cap.

Each pack contains one single-use vial.

BENDAMUSTINE VIATRIS 25 mg: AUST R 320951

BENDAMUSTINE VIATRIS 100 mg: AUST R 320950

Who distributes BENDAMUSTINE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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