Gazyva®

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.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using Gazyva?

Gazyva contains the active ingredient obinutuzumab. Gazyva is used to:
- treat chronic lymphocytic leukaemia (CLL)
- treat follicular lymphoma (FL) either in patients who have not been treated before or in patients who are no longer responding to treatment with another medicine called rituximab
- reduce the severity of cytokine release syndrome (CRS), a possible serious side effect of glofitamab treatment
- treat adult patients with active lupus nephritis (LN) together with other medicines.

For more information, see Section 1. Why am I using Gazyva? in the full CMI.

2. What should I know before I use Gazyva?

Do not use if you have ever had an allergic reaction to Gazyva 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 Gazyva? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Gazyva 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 Gazyva given?

Gazyva must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse. You will be given Gazyva by infusion into a vein (intravenous (IV) infusion). The number of infusions you will be given depends on why you are being given Gazyva and how you respond to the treatment. Before you receive Gazyva you will be given other medicines to help reduce the severity of possible infusion reactions. More instructions can be found in Section 4. How is Gazyva given? in the full CMI.

5. What should I know while using Gazyva?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are using Gazyva. • Tell your doctor or nurse immediately if you have any signs or symptoms of an infusion reaction or allergic reaction, or heart problems. • Tell your partner or caregiver you are receiving Gazyva and ask them to tell you if they notice any changes in your movement or behaviour. If they notice any changes you should tell your doctor about them immediately. • Tell your doctor if you become pregnant or intend to start a family while receiving Gazyva, if you intend to breast feed whilst receiving Gazyva, or if you intend to vaccinate your baby and were pregnant with your baby whilst receiving Gazyva. • Tell your doctor if you feel Gazyva is not helping your condition
Things you should not do	• Do not stop your Gazyva treatment without talking to your doctor first. • Do not take any other medicines, whether they require a prescription or not without first telling your doctor or consulting with a pharmacist

For more information, see Section 5. What should I know while using Gazyva? in the full CMI.

6. Are there any side effects?

Serious side effects include reactions such as swelling of the face, lips, tongue, throat or other parts of the body, trouble breathing, wheezing or coughing. 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.

WARNING: Progressive Multifocal Leukoencephalopathy

Progressive Multifocal Leukoencephalopathy (PML) is a rare, serious brain infection that can cause severe disability or even death. PML is a rare side effect that can occur whilst receiving Gazyva. Tell your partner or caregiver you are receiving Gazyva and ask them to tell you if they notice any changes in your movement or behaviour. If they notice any changes you should tell your doctor about them immediately

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Gazyva®

Active ingredient(s): obinutuzumab

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Gazyva?

Gazyva contains the active ingredient obinutuzumab. Gazyva belongs to a group of medicines known as monoclonal antibodies. Monoclonal antibodies are proteins which specifically recognise and bind to other unique proteins in the body.

Gazyva is used to:

- treat chronic lymphocytic leukaemia (CLL)
- treat follicular lymphoma (FL) either in patients who have not been treated before or in patients who are no longer responding to treatment with another medicine called rituximab
- reduce the severity of cytokine release syndrome (CRS), a possible serious side effect of glofitamab treatment
- treat adult patients with active lupus nephritis (LN) together with other medicines.

Chronic lymphocytic leukaemia (CLL) and follicular lymphoma (FL)

Gazyva recognises and attaches to a protein called CD20 which is found on the surface of white blood cells known as B lymphocytes. During the process of binding to the protein, the abnormal growth of the B lymphocytes is stopped. It is the abnormally growing B lymphocytes that are responsible for CLL and FL.

For CLL Gazyva is used with the chemotherapy medicine chlorambucil. For FL Gazyva is first given with chemotherapy medicines and then on its own.

Reduce the severity of cytokine release syndrome (CRS), a possible side effect of glofitamab treatment

Gazyva reduces the number of B lymphocytes before treatment with glofitamab, a medicine given to treat diffuse large b-cell lymphoma (DLBCL).

Lupus nephritis (LN)

LN is a type of kidney disease where the body's own immune system attacks the kidneys by mistake. Gazyva reduces the amount of B-lymphocytes, a kind of immune system cell that is involved in some symptoms of LN.

Gazyva is given to patients with LN together with other medicines. This slows down or stops the immune system from attacking healthy kidney cells.

For further information about any other medicines used with Gazyva please ask your doctor, nurse or pharmacist for the Consumer Medicine Information (CMI) for these medicines.

2. What should I know before I use Gazyva?

Warnings

Do not use Gazyva if:

- you are allergic to obinutuzumab, or any of the ingredients listed at the end of this leaflet.
- you have had an allergic reaction to any other proteins that are of mouse origin

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

Check with your doctor if:

- you have an infection, or a history of a recurring or long-term infection such as hepatitis B
- you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immunosuppressive medicines

- you are taking or have taken medicines which affect your immune system, you may have an increased risk of infections. There have been reports of a rare, serious brain infection called PML (progressive multifocal leukoencephalopathy) usually affecting people with a weakened immune system. Your chance of getting PML may be higher if you are treated with medicines that weaken the immune system, including Gazyva. PML can cause severe disability or even death.
- you have a history of heart disease with:
    - cardiac arrhythmias (abnormal beating of the heart)
    - angina (chest pain)
    - heart failure or a recent heart attack
- you are taking medicine to control blood pressure
- you are taking medicine to prevent blood clots
- you have pre-existing lung disease
- you have kidney disease
- you have liver disease
- you intend to have or have had immunisation with any vaccine
- you are allergic to any other medicines or any other substances such as foods, preservatives or dyes
- 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 for them. See additional information under Section 6. Are there any side effects?

Pregnancy

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

It is not known whether Gazyva is harmful to an unborn baby. It is not recommended that you are given Gazyva while you are pregnant.

If you are of child bearing potential, it is recommended that you do not become pregnant for 18 months following the end of treatment with Gazyva.

If you are of child bearing potential, it is recommended that you use effective contraceptive methods during treatment and for up to 18 months following the end of treatment with Gazyva.

Breastfeeding

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

It is not known if Gazyva passes into breast milk. It is recommended that you discontinue breast feeding while you are treated with Gazyva and for 18 months after your final infusion of Gazyva.

Use in children

The safety and efficacy of Gazyva in children and adolescents under 18 years of age have not been established.

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.

As Gazyva may cause a temporary drop in your blood pressure, your doctor may advise you to temporarily stop taking your blood pressure medicine before you are given Gazyva.

Gazyva can reduce the number of platelets in your blood. Taking medicine to prevent blood clots while you are receiving Gazyva may further reduce the number of platelets. This may cause life-threatening bleeding. Your doctor will supervise you closely during treatment with Gazyva.

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

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

4. How is Gazyva given?

Follow all directions given to you by your doctor or nurse carefully.

They may differ from the information contained in this leaflet.

Gazyva must be prepared by a healthcare professional and will be given in a hospital or clinic by a doctor or nurse. Gazyva is given by infusion into a vein (intravenous (IV) infusion).

How much and when to take Gazyva

Your doctor will decide how many infusions you need and the duration of the infusions.

Your doctor may adjust your infusion depending on how well each one is tolerated.

You will be closely monitored during each infusion.

Before you receive Gazyva you will be given other medicines to help reduce the severity of possible infusion reactions.

For chronic lymphocytic leukaemia (CLL)

The first infusion: you will be given 100 mg of Gazyva by IV infusion over 4 hours.

The second infusion: if the first infusion was well tolerated, you will be given 900 mg of Gazyva by IV infusion, either on the same day as the first infusion or a day later.

Subsequent infusions: if the previous infusion was well tolerated, you will be given 1000 mg of Gazyva by IV infusion.

For follicular lymphoma (FL)

The first infusion: you will be given 1000 mg of Gazyva by IV infusion.

Subsequent infusions: if the first infusion was well tolerated, you will be given 1000 mg of Gazyva by IV infusion.

Maintenance treatment: if you respond to initial treatment your doctor may decide to continue your treatment with Gazyva.

You may receive Gazyva once every 2 months for up to 2 years.

For pre-treatment to reduce the severity of Cytokine Release Syndrome (CRS) induced by glofitamab

You will be given a single 1000 mg dose of Gazyva by IV infusion 7 days before your glofitamab treatment begins.

For lupus nephritis (LN)

You will start Gazyva with 2 infusions, 2 weeks apart. 24 weeks after you started Gazyva, you will have another 2 infusions, 2 weeks apart. Thereafter, you will have 1 infusion, every 6 months. Each infusion is 1000 mg. Your doctor will decide how long you will receive treatment for.

If you miss a dose

As Gazyva is given under the supervision of your doctor, you are unlikely to miss a dose. However, if you forget or miss your appointment to receive Gazyva, you should not wait until the next planned dose but make another appointment as soon as possible.

If you use too much Gazyva

As Gazyva is given under the supervision of your doctor, it is very unlikely that you will be given too much. However, if you experience any side effects after being given Gazyva, tell your doctor immediately.

5. What should I know while using Gazyva?

Things you should do

Tell your doctor or nurse immediately if you have any signs or symptoms of an infusion reaction or allergic reaction, or heart problems.

Some signs and symptoms can include:

- swelling of your face, lips, tongue or throat with difficulty breathing
- swelling of other parts of your body
- shortness of breath, wheezing or trouble breathing
- rash, itching or hives on the skin
- feeling sick (nausea)
- fever, chills
- feeling tired
- headache
- chest pain
- abnormal or irregular heartbeat

Tell your partner or caregiver you are receiving Gazyva and ask them to tell you if they notice any changes in your movement or behaviour. If they notice any changes you should tell your doctor about them immediately.

Your doctor may need to perform some tests and alter your treatment.

Tell all doctors, dentists, nurses and pharmacists who are treating you that you are receiving Gazyva.

Tell your doctor if you become pregnant or intend to start a family while receiving Gazyva, if you intend to breast feed whilst receiving Gazyva, or if you intend to vaccinate your baby and were pregnant with your baby whilst receiving Gazyva.

Tell your doctor if you feel that Gazyva is not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will perform regular blood tests.

Things you should not do

Do not stop your Gazyva treatment without talking to your doctor first.

Do not take any other medicines, whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

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

Gazyva is unlikely to cause any problems with your ability to drive or operate machinery. However if you get any signs or symptoms of an infusion reaction or allergic reaction, or heart problems, you should refrain from driving or operating machinery until the reaction stops.

Looking after your medicine

Gazyva will be stored in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C and 8°C.

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.

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

If you are 65 years of age or older or suffer problems with your kidneys you may have an increased chance of getting side effects.

You may experience side effects during an infusion or after an infusion, these can be serious or less serious.

Serious side effects

Serious side effects	What to do
During an infusion: • swelling of your face, lips, tongue or throat with difficulty breathing • swelling of other parts of your body • shortness of breath, wheezing or trouble breathing • rash, itching or hives on the skin	**Tell your doctor or nurse immediately if you notice any of these while receiving an infusion.** These may be serious side effects. You may need

Serious side effects	What to do
• vomiting or feeling sick (nausea) • fever, flushing or chills • diarrhoea • cough or throat irritation • feeling tired • headache • chest pain • dizziness or light headedness • abnormal or irregular heartbeat	medical attention.
After an infusion: • swelling of your face, lips, tongue or throat with difficulty breathing • swelling of other parts of your body • shortness of breath, wheezing or trouble breathing • skin problems including rash, itchiness or hives, hardened or discoloured skin lesions which may increase in size • stomach cramps or pains • severe or bloody diarrhoea • nausea and vomiting including vomiting blood or material that looks like coffee grounds • fever, chills • severe coughing • abnormal or irregular heartbeat • chest pain • bleeding or bruising more than normal • blood clots • feeling dizzy or lightheaded • one or a combination of the following: confusion, disorientation or memory loss, changes in the way you move, walk or talk, decreased strength or progressive weakness in your body, blurred or loss of vision.	**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these signs after an infusion. These may be serious side effects.** You may need medical attention.

Less serious side effects

Less serious side effects	What to do
After an infusion: • frequent infections (from reduced immunity) such as fever, severe chills, respiratory infections (including pneumonia), shingles, mouth ulcers or urinary infections, skin and ear infections • pain in mouth or throat • runny or stuffy nose or stuffy chest	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• joint, bone or muscle pain • arm, leg or back pain • headache • diarrhoea, constipation, abdominal discomfort or pain, or haemorrhoids • urinary incontinence or pain • increased weight • persistent cough • hair loss • night sweats • itchy skin • red eye • sleeplessness and/or feeling tired • feeling depressed or anxious	

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 Gazyva contains

Active ingredient (main ingredient)	obinutuzumab.
Other ingredients (inactive ingredients)	histidine histidine hydrochloride monohydrate trehalose dehydrate poloxamer 188
Potential allergens	**Refer to your healthcare professional for further advice**

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

What Gazyva looks like

Gazyva is a clear, colourless to slightly brownish liquid. Gazyva is supplied as a single-dose glass vial containing 40 mL of solution for intravenous infusion (25 mg/mL). It is diluted before infusion into a vein. (AUST R 210562).

Who distributes Gazyva

Gazyva is distributed by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney, NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

www.medinfo.roche.com/australia Please check with your pharmacist for the latest Consumer Medicine Information (CMI).

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