Gazyva®

Contains the active ingredient obinutuzumab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gazyva. 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 Gazyva 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.
You may need to read it again.

What Gazyva is used for

Gazyva contains an active ingredient called obinutuzumab.

Gazyva belongs to a group of medicines known as anti-neoplastic (or anti-cancer) agents. There are many different classes of anti-neoplastic agents. Gazyva belongs to a class called 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). It is also used to 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.

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

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

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

This medicine is not addictive.

Before you are given Gazyva

If you are not sure whether you should start taking this medicine, talk to your doctor.

When you must not be given Gazyva

Do not use Gazyva:

- if you have had an allergic reaction to Gazyva or any of the ingredients listed at the end of this leaflet
- if 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
- **if the package is torn or shows signs of tampering**
- **if the expiry date (EXP) printed on the pack has passed**
  If you take this medicine after the expiry date has passed it may not work as well.

Before you are given Gazyva

Tell your doctor if:

- **you have an infection, or a history of a recurring or long-term infection such as Hepatitis B**
  You may have a greater chance of getting an infection during or after treatment with Gazyva.
- **you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immunosuppressive medicines**
  If 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
  Your doctor will supervise you closely during treatment with Gazyva.
- **you are taking medicine to control blood pressure**
  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.
- **you are taking medicine to prevent blood clots**
  Gazyva can reduce the number of platelets in your blood, which may cause life-threatening bleeding.
- **you have pre-existing lung disease**
  You may have a greater chance of breathing difficulties during treatment with Gazyva.
  Your doctor will supervise you closely during treatment with Gazyva.
- **you have kidney disease**
  You may have a greater chance of suffering a side effect during treatment with Gazyva if your kidneys are not functioning normally.
  Your doctor will supervise you closely during treatment with Gazyva.
- **you have liver disease**
  The safety and efficacy of Gazyva have not been established in people with liver problems.
- **you intend to have or have had immunisation with any vaccine**
  Some vaccines should not be given at the same time as Gazyva or in the months after you receive Gazyva. Your doctor will check if you should have any vaccines before you receive Gazyva.
  It is not known if Gazyva will affect your normal response to a vaccine.
- **you are allergic to any other medicines or any other substances such as foods, preservatives or dyes**
- **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.
- **you are breast feeding or plan to breast feed**
  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.

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

Use in children

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought without a prescription from a 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.

How Gazyva is 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 slow infusion into a vein (intravenous (IV) infusion). The number of infusions you will be given depends on 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.

For 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.

The duration of the infusion and when you receive the second infusion will be determined by your doctor.

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

The duration of the infusion and when you receive the infusion will be determined by your doctor.

You will be closely monitored during each infusion.

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

For 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.

The duration of each infusion and when you receive the infusion will be determined by your doctor.

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.

You will be closely monitored during each infusion.

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

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 take too much (overdose)

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.

While you are receiving Gazyva

Things you must 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 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.

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 must not do

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

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

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

Things to be careful of

Be careful driving or operating machinery until you know how Gazyva affects you.
Gazyva generally does not cause any problems with your ability to drive or operate machinery. However if you experience any of the reactions listed under the section Things you must do you should refrain from driving or operating machinery until the reaction stops.

Side effects

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

Gazyva helps most people with CLL, or FL which has not been treated before or which is no longer responding to treatment with rituximab, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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.

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

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

During an infusion

Tell your doctor or nurse immediately if you notice any of the following while receiving 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
- 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

These may be serious side effects. You may need medical attention.

After an infusion

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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.

These may be serious side effects. You may need medical attention.

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

- frequent infections such as fever, severe chills, respiratory infections (including pneumonia), shingles, mouth ulcers or urinary infections
- pain in mouth or throat
- runny or stuffy nose or stuffy chest
- 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

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. Others may occur in some people and there may be some side effects not yet know.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor, nurse or pharmacist if you don't understand anything in this list.

Product description

Storage

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

Availability

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.

What Gazyva looks like

Gazyva is a clear, colourless to slightly brownish liquid.

Ingredients

Each vial of Gazyva contains 1000 mg of the active ingredient obinutuzumab.

It also contains:

- histidine
- histidine hydrochloride monohydrate
- trehalose dehydrate
- poloxamer 188

Distributor

Manufacturer/Distributor/ Supplier

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

Please check with your pharmacist for the latest Consumer Medicine Information (CMI).

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