COLUMVI®

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. 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 COLUMVI?

COLUMVI contains the active ingredient glofitamab. COLUMVI is used to treat adults with a cancer called diffuse large B-cell lymphoma (DLBCL). COLUMVI can be given alone (monotherapy) or with chemotherapy medicines. COLUMVI is used with medicines gemcitabine and oxaliplatin when the cancer has come back (relapsed) or did not respond to previous treatments (refractory) and when you cannot receive a stem cell transplant. COLUMVI is registered to be used alone when the cancer has come back (relapsed) or did not respond to previous treatments (refractory) and when you have received two or more prior treatments. For more information, see Section 1. Why am I using COLUMVI? in the full CMI.

2. What should I know before I am given COLUMVI?

You must not be given COLUMVI if you have ever had an allergic reaction to COLUMVI or any of the ingredients listed at the end of the CMI. You must not be given COLUMVI if you have an active infection. **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 COLUMVI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COLUMVI 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 COLUMVI given?

You will be given COLUMVI under the supervision of a doctor experienced in cancer treatment, in a hospital or clinic. You will be given up to 12 treatment cycles of COLUMVI via an intravenous infusion. Each cycle lasts 21 days. Your doctor will begin COLUMVI treatment with a single infusion of another medicine called obinutuzumab and a low dose of COLUMVI and will gradually increase it to the full dose. More instructions can be found in Section 4. How is COLUMVI given? in the full CMI.

5. What should I know while using COLUMVI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using COLUMVI. • Pay attention to serious side effects. Some side effects can sometimes be life-threatening and may happen any time during COLUMVI treatment
Things you should not do	• Do not miss any appointments.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how COLUMVI affects you.

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

6. Are there any 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. Serious side effects include; Cytokine release syndrome; fever, fast heartbeat, feeling dizzy or light-headed, chills, shortness of breath. Neurologic toxicity including ICANS; being confused, disorientation, sleepiness, change in consciousness level. Haemophagocytic lymphohistiocytosis; fever, lymph node enlargement, breathing problems, or easy bruising. Progressive multifocal leukoencephalopathy; memory loss, trouble speaking, difficulty walking or problems with eyesight. Infection; fever, chills, difficulty breathing, burning pain during urination, confusion. Tumour flare; tender swollen lymph nodes, chest pain, difficulty breathing, tumour site pain. Tumour lysis syndrome; weakness, shortness of breath, confusion, irregular heartbeat, muscle cramps. Reduced levels of neutrophils, increased liver enzymes, bowel problems, inflammation in the lungs or numbness, tingling, a burning sensation, pain, discomfort or weakness and/or difficulty walking.

▼ 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.

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITY INCLUDING IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME (ICANS)

COLUMVI can cause serious side effects, including Cytokine Release Syndrome (CRS) and neurologic problems like confusion, seizures, or difficulty speaking (known as ICANS). These side effects can be life-threatening. To reduce the risk of CRS, your doctor will give you another medicine, obinutuzumab, 7 days before your first dose of COLUMVI. You must not take COLUMVI if you have an active infection or inflammatory condition. Follow your doctor's instructions carefully. Call your doctor or get emergency help immediately if you experience any of these symptoms: fever, chills, fast heartbeat, feeling dizzy or light-headed, shortness of breath, being confused, disorientation, sleepiness or change in consciousness level. Your doctor will monitor and treat these side effects if they occur.

COLUMVI®

Active ingredient(s): glofitamab

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using COLUMVI?

COLUMVI contains the active ingredient glofitamab.

COLUMVI is used to treat a type of blood cancer called diffuse large B-cell lymphoma (DLBCL).

COLUMVI is approved for use with the medicines gemcitabine and oxaliplatin to treat adults with DLBCL when the cancer has come back (relapsed) or has never responded (refractory) to one or more previous treatments and when you cannot receive a stem cell transplant.

COLUMVI has approval in Australia when used alone (monotherapy) to treat adults with DLBCL when the cancer has come back (relapsed) or did not respond to two or more previous treatments (refractory).

DLBCL is a cancer of a part of your immune system (the body's defenses).

- It affects a type of white blood cell called 'B cells'. Normally B cells help the body fight infection.
- In DLBCL, B cells multiply in an uncontrolled manner and build up in your tissues.

This medicine binds to the surface of the cancerous B cells and also to the surface of 'T cells' (another type of white blood cell that help your immune system fight infections). This binding on two targets activates T cells and causes them to multiply, which leads to the rapid breakdown of the cancerous B cells.

2. What should I know before I am given COLUMVI?

Warnings

Do not use COLUMVI if:

- you are allergic to glofitamab, or any of the ingredients listed at the end of this leaflet.

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

Check with your doctor if you:

- take any medicines for any other condition
- have an infection, including a long-lasting infection (chronic), or an infection which keeps coming back (recurring)
- have or had any kidney, liver or heart problems
- are due to have a vaccine

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

- Check with your doctor if you are pregnant or intend to become pregnant.
- You should not be given COLUMVI if you are pregnant. This is because it is possible that COLUMVI could harm your unborn baby.

If you could become pregnant, you must use effective contraception while you are being treated with COLUMVI and for 2 months after the last dose.

If you become pregnant while you are being treated with COLUMVI tell your doctor immediately.

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

Do not breastfeed while receiving COLUMVI and for at least 2 months after the last dose. This is because it is not known if this medicine can pass into breast milk and harm your baby.

Other medications given with COLUMVI may have different recommendations for pregnancy and breastfeeding.

Children and adolescents

This medicine should not be given to children and adolescents below 18 years of age. This is because COLUMVI has not been studied in this age group.

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.

Tell your doctor or nurse if you are due to have a vaccine, or you know you may need to have a vaccine in the near future.

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

4. How is COLUMVI given?

You will be given COLUMVI under the supervision of a doctor experienced in cancer treatment, in a hospital or clinic.

Medicines given before COLUMVI treatment

- Seven days before starting COLUMVI treatment, you will be given another medicine, obinutuzumab, to deplete the B cells in your blood in order to prevent cytokine release syndrome by preparing the immune system for COLUMVI. Cytokine release syndrome is a group of symptoms caused by small proteins called cytokines, released in your body by immune cells during inflammation.
- During the 30 to 60 minutes before you are given COLUMVI, you should be given other medicines (pre-medication) to help reduce reactions associated with cytokine release syndrome.
- These medicines may include:
    - An anti-inflammatory medicine (corticosteroid) such as dexamethasone
    - A fever-reducing medicine such as paracetamol
    - An antihistamine such as diphenhydramine

How much and how often you will receive COLUMVI

When COLUMVI is given alone or with the medicines gemcitabine and oxaliplatin, you will be given up to 12 treatment cycles of COLUMVI via an intravenous infusion. Each cycle lasts 21 days.

Your doctor will begin COLUMVI treatment with a lower dose and will gradually increase it to the full dose.

A typical schedule is shown below.

Cycle 1: This will include a pre-treatment of obinutuzumab and 2 low doses of COLUMVI during the 21 days:

- Day 1: pre-treatment with obinutuzumab
- Day 8: 2.5 mg starting dose of COLUMVI
- Day 15: 10 mg intermediate dose of COLUMVI

Cycle 2 to Cycle 12: This will be just one dose in the 21 days:

- Day 1: 30 mg full dose of COLUMVI

How COLUMVI is given and monitoring

COLUMVI is given as a drip into a vein (an intravenous infusion). Your doctor will adjust the time required for infusion depending on how you respond to treatment.

- Your first infusion will be given over 4 hours.
- For the first infusion, your doctor will monitor you carefully during and for 10 hours after completion of infusion.
- This is to watch for any potential signs or symptoms of cytokine release syndrome.
- Following infusions will be given over 4 hours and you may be monitored after completion of infusion. This will be necessary if you have had moderate or severe cytokine release syndrome with your previous dose.
- If you do not experience cytokine release syndrome after 3 doses, your doctor may give the following infusions over 2 hours.

If you miss a dose of COLUMVI

If you miss an appointment, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

Before stopping COLUMVI treatment

Speak with your doctor before stopping treatment. This is because stopping treatment may make your condition worse.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

If you are given too much COLUMVI

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

5. What should I know while using COLUMVI?

Things you should do

Carry your patient card at all times.

Remind any doctor, dentist or pharmacist you visit that you are using COLUMVI.

Pay attention to serious side effects.

Some side effects can sometimes be life-threatening and may happen any time during COLUMVI treatment.

Call your doctor straight away if you experience any of the following serious side effects while being treated with COLUMVI:

- fever, fast heartbeat, feeling dizzy or lightheaded, chills, shortness of breath. These may be symptoms of a serious condition known as cytokine release syndrome.
- being confused, disorientation, sleepiness, or change in consciousness level. These symptoms could be a sign of a problem with your nervous system caused by your immune cells. This is known as neurologic toxicity including immune effector cell-associated neurotoxicity syndrome (ICANS) which can be caused by certain medicines.
- memory loss, trouble speaking, difficulty walking, or problems with eyesight. These may be signs of a condition called progressive multifocal leukoencephalopathy (PML), a serious and potentially fatal brain infection. These symptoms may overlap or be similar to neurologic toxicity symptoms mentioned above.
- if you develop fever, chills, difficulty breathing, burning sensation while passing urine. These may be signs of an infection. Some infections may be life-threatening or fatal.
- fever, lymph node enlargement, breathing problems, or easy bruising, these may be signs of a condition called haemophagocytic lymphohistiocytosis where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes. It can lead to enlarged liver and/or spleen and kidney abnormalities which can cause pain and swelling in the abdomen or yellow skin or eyes.
- kidney problems (weakness, shortness of breath, fatigue and confusion), heart problems (fluttering of the heart or a faster or slower heartbeat), vomiting or diarrhoea and tingling in the mouth, hands or feet. These may be signs of a condition called tumour lysis syndrome.
- your cancer appears to become worse and you develop tender swollen lymph nodes, chest pain, cough, inability to breathe easily, or pain at the site of the tumour. These may be symptoms of tumour flare.

Things you should not do

- Do not miss any of your scheduled appointments.

Driving or using machines

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

COLUMVI is not likely to affect your ability to drive, cycle or use any tools or machines.

However, if you have symptoms of cytokine release syndrome (such as fever, fast heartbeat, feeling dizzy or lightheaded, chills or shortness of breath) or neurologic toxicity including ICANS– do not drive, cycle or use any tools or machines until you feel better.

Looking after your medicine

This medicine will be stored by your doctor at the hospital or clinic.

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
Blood tests: • reduced levels in blood tests of lymphocytes (a type of white blood cell), that may affect the body's ability to fight infection • reduced red blood cells (anaemia), which may cause tiredness, feeling unwell and pale skin • reduced platelets (a type of blood cell), which may cause unusual bruising or bleeding • low sodium levels in blood tests, which may cause tiredness, muscle twitching or cramps • low levels of phosphate, magnesium, calcium, potassium or sodium • low level of antibodies called "immunoglobulins", which can make it harder for the body to fight infections **Gastrointestinal/digestive system:** • constipation • diarrhoea • feeling sick (nausea) • vomiting • abdominal (belly) pain • inflammation of the pancreas **Skin and muscle:** • rash • pain in the muscles and bones **Nervous system:** • sleepiness	**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
• headache • trembling • confusion **Infection:** • new or recurring viral infections, such as lung infection, shingles, cytomegalovirus infection • bacterial infections, such as urinary tract infection (burning pain when passing urine), infection in or around the stomach. • respiratory tract infections, such as runny nose, sore throat, sinus infections, chest colds or lung infection (pneumocystis jirovecii pneumonia) may include fever, cough and difficulty breathing. • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2).	

Serious side effects

Serious side effects	What to do
Cytokine release syndrome: • fever, fast heartbeat, feeling dizzy or lightheaded, chills, shortness of breath, fever with low levels of neutrophils (a type of white blood cell). **Neurologic toxicity including ICANS:** • being confused, disorientation, sleepiness, and change in consciousness level. **Haemophagocytic lymphohistiocytosis:** • fever, lymph node enlargement, breathing problems, or easy bruising. **Progressive multifocal leukoencephalopathy;** • memory loss, trouble speaking, difficulty walking or problems with eyesight, these symptoms may overlap or be similar to neurologic toxicity symptoms mentioned above	**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.**
Tumour flare: • cancer worsening, swollen lymph nodes, chest pain, cough, breathing difficulty, tumour site pain. **Tumour lysis syndrome:** • weakness, breathlessness, fatigue and confusion), heart problems (fluttering of the heart or a faster or slower heartbeat), vomiting or diarrhoea and tingling mouth, hands or feet. **Infections:** • fungal infections such as oral thrush, difficulty or pain when swallowing or eating, white patches on inner cheeks, tongue, roof of mouth and throat, redness or soreness, cotton-like feeling in the mouth, loss of taste, cracking and redness at the corners of the mouth • infection in blood (sepsis), which may cause fever, chills and confusion. **Bleeding:** • bleeding in the stomach or gut (gastrointestinal haemorrhage), which may cause black stools or blood in vomit. **Nervous system:** • swelling of the spinal cord (myelitis), which may cause muscle weakness or numbness • numbness, tingling, a burning sensation, pain, discomfort or weakness and/or difficulty walking (peripheral neuropathy). **Blood tests:** • reduced levels of neutrophils (a type of white blood cell), which may cause fever or any symptoms of an infection • increased levels in blood tests of liver enzymes, which may be a sign of an inflamed liver and bilirubin (yellow substance in blood), which	

Serious side effects	What to do
may cause yellowing of skin or eyes, and dark urine. **Gastrointestinal/digestive system:** • inflammation of the large bowel, which may cause abdominal pain, bloody stools and the urge to have a bowel movement. **Lungs:** • Inflammation in the lungs (pneumonitis).	

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 COLUMVI contains

Active ingredient (main ingredient)	glofitamab
Other ingredients (inactive ingredients)	histidine histidine hydrochloride monohydrate methionine sucrose polysorbate 20 (E432) water for injections
Potential allergens	nil

Tell your doctor or nurse if you are allergic to any of these ingredients in this medicine.

What COLUMVI looks like

COLUMVI is a colourless, clear solution provided in a glass vial.

COLUMVI 2.5 mg/2.5 mL: Each vial contains 2.5 milligrams of glofitamab (in 2.5 mL) (AUST R 389650)

COLUMVI 10 mg/10 mL: Each vial contains 10 milligrams of glofitamab (in 10 mL) (AUST R 392331)

Who distributes COLUMVI

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

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