

## 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.

### 1. Why am I using Columvi?

Columvi contains the active ingredient glofitamab. Columvi is provisionally registered to treat adults with a cancer called diffuse large B-cell lymphoma (DLBCL). It is used when the cancer has come back (relapsed) or the cancer did not respond to previous 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	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Columvi.</li><li>Pay attention to serious side effects. Some side effects can sometimes be life-threatening and may happen any time during Columvi treatment.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>Do not miss any appointments.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>If you have symptoms of cytokine release syndrome (such as fever, fast heartbeat, feeling dizzy or lightheaded, chills or shortness of breath) – do not drive, cycle or use any tools or machines until you feel better.</li></ul>

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
- Cytokine release syndrome; symptoms include fever, fast heartbeat, feeling dizzy or lightheaded, chills, shortness of breath
- Neurologic toxicity including immune effector cell-associated neurotoxicity (ICANS); symptoms include confusion, disorientation, sleepiness, change in consciousness level.
- Infection; symptoms include fever, chills, difficulty breathing, burning pain when passing urine
- Tumour flare; symptoms include tender swollen lymph nodes, chest pain, inability to breathe easily, pain at the site of the tumour
- Tumour lysis syndrome; symptoms include weakness, shortness of breath, feeling confused, irregular heartbeat, muscle cramps

▼ 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](http://www.tga.gov.au/reporting-problems).

# 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 has provisional approval in Australia to treat adults with a cancer called diffuse large B-cell lymphoma (DLBCL). It is used when:

- the cancer has come back (relapsed) or
- the cancer did not respond to previous treatments.

The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

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

- It affects a type of white blood cell called 'B cells'
- 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). 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 breast-feed 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.

### 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.

Cytokine release syndrome is a group of symptoms caused by small proteins called cytokines, released in your body during inflammation.

- During the 30 to 60 minutes before you are given Columvi, you may be given other medicines (pre-medication) to help reduce reactions associated with cytokine release syndrome.
- These medicines may include:
  - A 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

- 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 - starting low Columvi dose of 2.5 mg
- Day 15 - the second low Columvi dose of 10 mg

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

- Day 1 - full Columvi dose of 30 mg

#### 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. Your doctor will monitor you carefully during the first

infusion and for 10 hours after completion of infusion. This is to watch for any signs or symptoms of cytokine release syndrome.

- You may be monitored after completion of your 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.
- confusion, 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).
- 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.

- 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
<p><b>Blood tests:</b></p> <ul style="list-style-type: none"> <li>• reduced levels of neutrophils (a type of white blood cell), which may cause fever or any symptoms of an infection</li> <li>• reduced red blood cells (anaemia), which may cause tiredness, feeling unwell and pale skin</li> <li>• reduced platelets (a type of blood cell), which may cause unusual bruising or bleeding</li> <li>• low sodium levels in blood tests, which may cause tiredness, muscle twitching or cramps</li> <li>• increased levels in blood tests of liver enzymes and bilirubin (yellow substance in blood),</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<p>which may cause yellowing of skin or eyes, and dark urine</p> <ul style="list-style-type: none"> <li>• low levels of phosphate, magnesium, calcium or potassium</li> </ul> <p><b>Gastrointestinal system:</b></p> <ul style="list-style-type: none"> <li>• constipation</li> <li>• diarrhoea</li> <li>• feeling sick (nausea)</li> <li>• vomiting</li> </ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"> <li>• rash</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• sleepiness</li> <li>• headache</li> <li>• trembling</li> <li>• confusion</li> </ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"> <li>• viral infections, such as lung infection, shingles</li> <li>• bacterial infections, such as urinary tract infection (burning pain when passing urine), infection in or around the stomach</li> <li>• infection in blood (sepsis), which may cause fever, chills and confusion</li> <li>• respiratory tract infections, such as runny nose, sore throat, sinus infections, chest colds or lung infection (pneumonia) may include fever, cough and difficulty breathing</li> </ul>	

### Serious side effects

Serious side effects	What to do
<p><b>Cytokine release syndrome:</b> Symptoms include fever, fast heartbeat, feeling dizzy or lightheaded, chills, shortness of breath, fever with low levels of neutrophils.</p> <p><b>Neurologic toxicity including ICANS:</b> Symptoms include symptoms include confusion, disorientation, sleepiness, and change in consciousness level.</p> <p><b>Tumour flare:</b> Symptoms include cancer worsening, swollen lymph nodes, chest pain, cough, breathing difficulty, tumour site pain</p> <p><b>Tumour lysis syndrome:</b></p>	<p><b>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.</b></p>

Serious side effects	What to do
<p>Symptoms include 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.</p> <p><b>Infections:</b></p> <ul style="list-style-type: none"> <li>• 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</li> </ul> <p><b>Bleeding:</b></p> <ul style="list-style-type: none"> <li>• bleeding in the stomach or gut (gastrointestinal haemorrhage), which may cause black stools or blood in vomit.</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>• swelling of the spinal cord (myelitis), which may cause muscle weakness or numbness.</li> </ul>	

**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](http://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

<b>Active ingredient (main ingredient)</b>	glofitamab
<b>Other ingredients (inactive ingredients)</b>	histidine histidine hydrochloride monohydrate methionine sucrose polysorbate 20 (E432) water for injections

<b>Potential allergens</b>	nil
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**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](http://www.medinfo.roche.com/australia)

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