

RIXIMYO®

for treatment of Rheumatoid Arthritis, Granulomatosis with Polyangiitis, Microscopic Polyangiitis

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.

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

1. WHY AM I USING RIXIMYO?

RIXIMYO contains the active ingredient rituximab (rch). RIXIMYO is used to treat rheumatoid arthritis (RA), granulomatosis with polyangiitis (Wegener's or GPA) and Microscopic polyangiitis (MPA).

For more information, see Section [1. Why am I using RIXIMYO?](#) in the full CMI.

2. What should I know before I use RIXIMYO?

Do not use if you have ever had an allergic reaction to rituximab 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 RIXIMYO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RIXIMYO 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 do I use RIXIMYO?

- RIXIMYO concentrated solution is diluted with sterile saline (sodium chloride) or dextrose solution before it is given as a slow infusion into a vein (intravenous infusion) by a healthcare professional.
- Before the infusion is given you will receive medicines to reduce the chance of any reactions to RIXIMYO.

More instructions can be found in Section [4. How do I use RIXIMYO?](#) in the full CMI.

5. What should I know while using RIXIMYO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are receiving RIXIMYO.• If you are a woman of child bearing potential, you must use effective contraceptive methods to prevent pregnancy during treatment with RIXIMYO and for 12 months after completing treatment.• Tell your partner or caregiver you are receiving RIXIMYO 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.
Things you should not do	<ul style="list-style-type: none">• Do not breast feed your infant during treatment with RIXIMYO and for 6 months after completing treatment.• 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	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how RIXIMYO affects you.
Looking after your medicine	<ul style="list-style-type: none">• RIXIMYO should be stored in the pharmacy or on the hospital ward. Each vial is intended for use in one patient on one occasion only.

For more information, see Section [5. What should I know while using RIXIMYO?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following during or after receiving an infusion (particularly during the first 2 hours of receiving the first infusion) and they worry you: fever, chills and severe shivering (most likely to occur), swelling of the tongue, face, lips, mouth or throat which may cause difficulty breathing or swallowing, itchy rash and/or pinkish, itchy swellings on the skin, difficulty breathing and/or shortness of breath, wheezing or coughing, dizziness or light-headedness, especially on standing up, high blood pressure, tremor, nausea (feeling sick) or vomiting, headache, fatigue (feeling tired) and/or feeling weak, rhinitis (a runny nose), flushing, fast heart beat, chest pain, stomach pain or discomfort, throat irritation.

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: Use of RIXIMYO may be associated with an increased risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Patients must be monitored for any new or worsening neurological symptoms or signs suggestive of PML. If such symptoms occur, further administration of RIXIMYO should be immediately suspended until a diagnosis of PML has been excluded. To establish or exclude a diagnosis of PML evaluation including MRI scan, CSF testing for JC viral DNA and repeat neurological assessments, should be considered. If a diagnosis of PML is confirmed, RIXIMYO must be permanently discontinued.

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for treatment of Rheumatoid Arthritis, Granulomatosis with Polyangiitis, Microscopic Polyangiitis

Active ingredient(s): rituximab (rch)

Consumer Medicine Information (CMI)

This leaflet provides important information about using RIXIMYO. 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 RIXIMYO.

Where to find information in this leaflet:

- [1. Why am I using RIXIMYO?](#)
- [2. What should I know before I use RIXIMYO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RIXIMYO?](#)
- [5. What should I know while using RIXIMYO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RIXIMYO?

RIXIMYO contains the active ingredient rituximab (rch). RIXIMYO is a monoclonal antibody. Monoclonal antibodies are proteins which specifically recognise and bind to other unique proteins in the body.

RIXIMYO is used to treat rheumatoid arthritis (RA), granulomatosis with polyangiitis (Wegener's or GPA) and Microscopic polyangiitis (MPA).

RA is an inflammatory disease of the joints, while GPA and MPA are inflammatory diseases of the blood vessels.

Rituximab works by binding to a protein on the surface of certain white blood cells known as B lymphocytes, which play a role in inflammation observed in RA, GPA and MPA. By binding to the protein, rituximab reduces the ability of B lymphocytes to cause inflammation.

In RA, rituximab can also slow down the damage to your joints and improve your ability to do your normal daily activities.

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 use RIXIMYO?

Warnings

Do not use RIXIMYO if:

- you are allergic to rituximab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other proteins that are of mouse origin
- you have a severe active infection at the moment
- you have a weak immune system
- you have severe heart failure or severe uncontrolled heart disease.

Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles.

If you are not sure if you should start receiving RIXIMYO, talk to your doctor.

Check with your doctor if you:

- **have an infection, or a history of a recurring or long-term infection such as hepatitis B**
- **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 leuko-encephalopathy) usually affecting people with a weakened immune system. Your chance of getting PML may be higher if you are treated with RIXIMYO and/or other medicines that weaken the immune system. PML can cause severe disability or even death.
- **have a history of heart disease with:**
 - angina
 - cardiac arrhythmias (abnormal beating of the heart)
 - congestive heart failureYour doctor will supervise you closely during treatment with RIXIMYO.
- **are taking medicine to control blood pressure**

RIXIMYO may cause a reduction in blood pressure at the beginning of treatment. Because RIXIMYO 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 RIXIMYO.

- **have pre-existing lung disease**
You may have a greater chance of breathing difficulties during treatment with RIXIMYO.
- **are 65 years of age or older, or suffer from kidney problems, and are being treated for GPA or MPA**
You may have an increased risk of serious side effects. Your doctor will monitor you closely during treatment.
- **intend to have or have had immunisation with any vaccine (e.g. measles, rubella, flu, vaccines for travel purposes)**
Some vaccines should not be given at the same time as RIXIMYO or in the months after you receive RIXIMYO. Your doctor will check if you should have any vaccines before you receive RIXIMYO.
- **are allergic to any other medicines or any other preservatives or dyes**

If you have not told your doctor about any of the above, tell him/ her before you are given RIXIMYO. Your doctor will decide whether it is safe for you to receive RIXIMYO.

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.

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

If you are a woman of child-bearing potential, you must use effective contraceptive methods to prevent pregnancy during treatment and for 12 months after completing treatment with RIXIMYO.

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

Rituximab passes into breast milk in very small amounts. As the long-term effects on breastfed infants are not known, for precautionary reasons, breast-feeding is not recommended during treatment with RIXIMYO and for 6 months after the treatment.

Use in children

The safety and effectiveness of rituximab have not been established in children.

Your doctor will discuss the risks and benefits of using this medicine in children.

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 RIXIMYO may cause a temporary drop in your blood pressure at the beginning of treatment, your doctor may advise you to temporarily stop taking your blood pressure medicine before you are given RIXIMYO.

It is not known if RIXIMYO will affect your normal response to a vaccine.

It is possible that after treatment with RIXIMYO you may experience allergic reactions if you are treated with other medications containing monoclonal antibodies.

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

4. How do I use RIXIMYO?

How RIXIMYO is given

- RIXIMYO concentrated solution is diluted with sterile saline (sodium chloride) or dextrose solution before it is given as a slow infusion into a vein (intravenous infusion) by a healthcare professional.
- Before the infusion is given you will receive medicines to reduce the chance of any reactions to RIXIMYO.
- The dose of RIXIMYO for treatment of RA is 1000 mg followed by a second dose of 1000 mg two weeks later. RIXIMYO should be used together with methotrexate when treating RA.
- Depending on the circumstances of your disease or response to the drug, your doctor may decide to give you an additional course of RIXIMYO.
- The dose of RIXIMYO for GPA and MPA patients is 375 mg per square metre of body surface area once a week for 4 weeks. RIXIMYO should be used together with glucocorticoids when treating GPA or MPA.

If you are given too much RIXIMYO

As RIXIMYO is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you think that you have been given too much RIXIMYO, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, 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 using RIXIMYO?

Things you should do

- If you are a woman of child bearing potential, you must use effective contraceptive methods to prevent pregnancy during treatment with RIXIMYO and for 12 months after completing treatment.
- Tell your doctor if you become pregnant while receiving RIXIMYO.
- Tell your partner or caregiver you are receiving RIXIMYO 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.
- 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.

Remind any doctor, dentist or pharmacist you visit that you are receiving RIXIMYO.

Things you should not do

- Do not breast feed your infant during treatment with RIXIMYO and for 6 months after completing treatment.
Rituximab passes into breast milk in very small amounts. The long-term effects on breastfed infants are not known.
- 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 RIXIMYO affects you.

RIXIMYO generally does not cause any problems with your ability to drive or operate machinery. However, as with many other medicines, RIXIMYO may cause dizziness in some people.

Looking after your medicine

- RIXIMYO should be stored in the pharmacy or on the hospital ward. Each vial is intended for use in one patient on one occasion only.
- The concentrated solution should be kept in a refrigerator at 2-8°C, but must not be frozen. The vial should be kept in the carton to protect it from light.
- If the diluted solution is not immediately given for infusion, it may be stored in a refrigerator at 2-8°C for up to 24 hours.
- RIXIMYO vials may be stored below 30°C for a single period of up to 7 days.
- Any unused portion in the vial or infusion bag should be discarded.

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
<ul style="list-style-type: none"> • fever, chills and severe shivering (most likely to occur) • swelling of the tongue, face, lips, mouth or throat which may cause difficulty breathing or swallowing • itchy rash and/or pinkish, itchy swellings on the skin • difficulty breathing and/or shortness of breath • wheezing or coughing • dizziness or light-headedness, especially on standing up • high blood pressure • tremor • nausea (feeling sick) or vomiting • headache • fatigue (feeling tired) and/or feeling weak • rhinitis (a runny nose) • flushing • fast heart beat • chest pain • stomach pain or discomfort • throat irritation. 	<p>Tell your doctor if you notice any of the following during or after receiving an infusion (particularly during the first 2 hours of receiving the first infusion) and they worry you.</p> <p>These side effects are temporary and less likely to occur after the first infusion.</p> <p>Your doctor may recommend that you take medication to prevent pain or allergy before you receive your RIXIMYO infusion.</p>
<ul style="list-style-type: none"> • aching muscles, muscle tenderness or weakness, muscle spasms • indigestion • painful, swollen joints • severe headache • high cholesterol • insomnia • diarrhoea • pins and needles, or decreased feeling in the skin 	<p>Tell your doctor if you notice any of the following and they worry you.</p>

<ul style="list-style-type: none"> infections e.g. urinary tract infections, colds or chest infections including pneumonia. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> infections with fever, severe chills, sore throat or mouth ulcers severe skin rash, itching, hives swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles one or a combination of the following: severe shortness of breath, severe difficulty breathing, severe wheezing, severe coughing severe stomach pain, nausea or vomiting vision loss associated with headaches, confusion and seizures 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. yellowing of skin and eyes, light coloured bowel motions, dark coloured urine memory loss, trouble thinking, difficulty walking or sight loss – these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML). fever, headache and stiff neck, incoordination (ataxia), personality change, hallucinations, altered consciousness, seizures or coma – these may be due to a serious brain infection (enteroviral meningoencephalitis), which can be fatal. 	<p>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.</p> <p>You may need urgent medical attention.</p>

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 or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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 RIXIMYO contains

Active ingredient (main ingredient)	rituximab (rch)
Other ingredients (inactive ingredients)	citric acid monohydrate, sodium chloride, polysorbate 80, sodium hydroxide and/or hydrochloric acid (for pH adjustment), water for injections.
Potential allergens	sodium chloride

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

What RIXIMYO looks like

RIXIMYO 100 mg/10 mL – clear, colourless to slightly yellowish, concentrated solution in 10 mL glass vials. Available in packs of 2 or 3 single-use vials (AUST R 281782)

RIXIMYO 500 mg/50 mL – clear, colourless to slightly yellowish, concentrated solution in 50 mL glass vials. Available in packs of 1 or 2 single-use vials (AUST R 281781)

Vial stopper not made with natural rubber latex.

Who distributes RIXIMYO

RIXIMYO is distribute in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

RIXIMYO is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand

Tel: 0800 726 369

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