

RIXIMYO

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

rituximab (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RIXIMYO.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.tga.gov.au

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What RIXIMYO is used for

RIXIMYO contains the active ingredient rituximab, which is a monoclonal antibodies.

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.

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

Before you start on RIXIMYO

When it must not be given to you

RIXIMYO is not suitable for you:

- **if you have had an allergic reaction to rituximab 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 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.

Before you are given it

Your doctor must know about all of the following before you are given RIXIMYO.

Tell 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**
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 RIXIMYO and/or other medicines that weaken the immune system. PML can cause severe disability or even death.

- **you 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.
- **you 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.
- **you have pre-existing lung disease**
You may have a greater chance of breathing difficulties during treatment with RIXIMYO.
- **you 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.
- **you 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.

- **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 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.
- **you are breastfeeding or plan 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.

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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

buy without a prescription from a 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.

Your doctor and pharmacist will have more information on medicines to be careful with or to avoid while undergoing treatment with 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 (overdose)

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 experience any side effects after being given RIXIMYO, tell your doctor immediately.

While you are receiving RIXIMYO

Things you must 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 all doctors, dentists and pharmacists who are treating you that you are 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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

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

RIXIMYO helps many people with RA, GPA or MPA but it may have unwanted side effects.

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

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

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

The following is a list of the more common side effects.

During or after an infusion

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.

These side effects are temporary and less likely to occur after the first infusion.

Your doctor may recommend that you take medication to prevent pain or allergy before you receive your RIXIMYO infusion.

The following is a list of other common side effects. Tell your doctor if you notice any of the following and they worry you:

- 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
- infections e.g. urinary tract infections, colds or chest infections including pneumonia

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

- 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.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

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 known.

Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in these lists.

After receiving RIXIMYO

Keep all of your appointments with your doctor so that your progress can be checked, any tests are made and further infusions can be given when needed.

Storage

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.

Product description

What it looks like

RIXIMYO is a clear, colourless to slightly yellowish, concentrated solution in 10 mL or 50 mL glass vials. It is available in packs of:

- Two or three 100 mg/10 mL single-use vials;
- One or two 500 mg/50 mL single-use vials.
Vial stopper not made with natural rubber latex.

Ingredients

RIXIMYO vials contain 10 mg of the active ingredient, rituximab (rch), per mL of concentrated solution. The solution also contains the following inactive ingredients:

- citric acid monohydrate
- sodium chloride
- polysorbate 80
- sodium hydroxide and/or hydrochloric acid (for pH adjustment)
- water for injections.

Sponsor

RIXIMYO is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia

Tel 1800 726 369

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100mg/10mL vial - AUST R 281782

500mg/50mL vial - AUST R 281781