RUXIENCE® (rituximab)







Getting started on my RUXIENCE treatment

This brochure has been designed to answer your questions and help you get the most out of your treatment.

It is important to read this brochure and keep it handy to help you understand your treatment. Also, it is important to be honest with your healthcare team about how you're doing on treatment. Speak to them when you have any questions or concerns about your treatment plan.

What is RUXIENCE used for?

RUXIENCE is an injectable medicine that is used to reduce signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate. RUXIENCE in combination with glucocorticoids or "steroids" is also used to reduce inflammation associated with severe Granulomatosis with Polyangiitis (GPA, also known as Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) and helps to control your disease.

How does RUXIENCE work?

B-cells are an important element in the immune system, helping the body to fight off infection. However, in diseases such as RA and GPA/MPA, the immune system acts abnormally. This may lead to an attack on normal healthy tissue, such as the joints. In GPA/MPA patients, the immune system can attack the respiratory tract (sinuses, nose, trachea [windpipe], and lungs), kidneys, eyes, nerves, and skin.



RUXIENCE is a monoclonal antibody. Antibodies are proteins that are produced to bind to another protein called an antigen. RUXIENCE binds to an antigen on the surface of a type of white blood cell, the B lymphocyte. When RUXIENCE binds to the surface of this cell, it causes the cell to die.

What formats are available for RUXIENCE?

RUXIENCE is available as a sterile liquid solution in single-use vials. It is available in two strengths:

100 mg/10 mL (10 mg/mL)



500 mg/50 mL (10 mg/mL)





How will I receive RUXIENCE?

RUXIENCE is not taken by mouth. It is given with fluids through an intravenous line. An intravenous line, or I.V., is a thin, plastic tube placed in a vein in your hand or arm. When RUXIENCE is given intravenously, it is called an infusion.

Your doctor has prescribed RUXIENCE after carefully studying your case. Other people may not benefit from taking this medicine, even though their medical problems may seem similar to yours.

Before the infusion is given, you will be given medicines to prevent or reduce possible reactions to RUXIENCE.

How often will I receive RUXIENCE?

Rheumatoid Arthritis

Each course of treatment is made up of two separate infusions that are given at least 2 weeks apart. Repeated courses of treatment with RUXIENCE are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more RUXIENCE.

Granulomatosis with Polyangiitis/Microscopic Polyangiitis RUXIENCE is administered as a weekly intravenous infusion for 4 weeks.



Important safety information

What should I know before using RUXIENCE?

Do not use RUXIENCE if you:

- are allergic to rituximab or proteins of similar origin or any other non-medicinal ingredient in RUXIENCE.
- have ever had a rare infection of the brain called progressive multifocal leukoencephalopathy (PML).

RUXIENCE is not recommended for use among patients with severe active infections.

RUXIENCE is not recommended unless patients' moderate-to-severe rheumatoid arthritis has not been controlled with medicines called tumour necrosis factor (TNF) antagonists.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RUXIENCE

Talk about any health conditions or problems you may have, including if you:

- have ever had a bad reaction to rituximab or any of the non-medicinal ingredients.
- are allergic to other medications, food, or dyes.
- have a history of heart disease, heart attack, or stroke.
- are taking any other medicines (including those not prescribed by the doctor).
- are taking or took another biologic medicine called a TNF antagonist or a DMARD (disease modifying anti-rheumatic drug).
- are taking medication to reduce blood pressure.
- are planning to be immunized with a vaccine during or after the completion of your RUXIENCE therapy.
- have a pre-existing lung disease as you may have a greater chance of breathing difficulties during your RUXIENCE treatment infusion.
- have a history of hepatitis B or current hepatitis B infection.
- have a history of chronic or recurrent infection.
- are pregnant, plan on becoming pregnant, or are breastfeeding a child.

This information will help your doctor and you decide whether you should use RUXIENCE and what extra care may need to be taken while you are on the medication.



Important safety information

What are possible side effects of RUXIENCE?

These are not all the possible side effects you may feel when taking RUXIENCE. If you experience any side effects not listed here, contact your healthcare professional. Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are receiving treatment with RUXIENCE.

The most common possible unwanted effects are infusion-related events:

- Fever and chills
- Nausea, vomiting, fatigue (feeling tired or weak), headache, skin rash, redness of
 the skin, itchiness, wheezing or tightness in the chest, shortness of breath, difficulty
 breathing, sensation of the tongue or throat swelling, throat irritation, rhinitis (runny
 nose), temporary low blood pressure, high blood pressure, flushing, dizziness on
 standing up, fast heartbeat, chest pain, pain in the mouth/throat, and swelling of
 the hands and feet.

If these unwanted effects occur, it is most common within 30 minutes to 2 hours after starting the first infusion but may also occur after the infusion has finished. The symptoms are usually mild to moderate, which can be easily treated. Rarely, these reactions can be severe. These unwanted side effects are less common after the first treatment.

These unwanted effects can be prevented or managed by:



• Slowing or interrupting your infusion of RUXIENCE. The treatment can be restarted once the symptoms have resolved.



• Giving a fever reducer, such as TYLENOL®, or an antihistamine, such as BENADRYL®, before each infusion of RUXIENCE. Sometimes additional medications need to be given to treat these unwanted effects.

Additionally:

- Your doctor may instruct you not to take your blood pressure medication 12 hours before and delay taking until after your infusion of RUXIENCE is complete. Please ask your doctor for specific instructions.
- Because some of the medications given with RUXIENCE may cause some dizziness or sleepiness, you should arrange for someone else to drive you home after each treatment.

In addition to the unwanted effects described above, there are certain adverse events identified that are specific to Granulomatosis with Polyangiitis/Microscopic Polyangiitis (GPA/MPA) patients, namely muscle spasms, increases in liver enzymes, and nose bleeds.

There are also possible unwanted effects that could be serious, but occur less commonly.

Some patients get infections after treatment. Often these are colds, but could be pneumonia or urinary infections. Some other effects might occur but are less likely, including pain in the tummy, back, chest, muscles and/or joints, or at the infusion site, feeling unwell, changes in blood pressure, changes in heart rate, diarrhea, indigestion, cramp, dizziness, tingling or numbness, anxiety or nervousness, cough, watery or itchy eyes, runny or itchy nose, sweating, or sinusitis.

Some patients also have some changes to blood tests, including a fall in the number of red cells, white cells, or both. Severe but rare reactions, in particular severe breathing difficulties and severe skin reactions including blistering, could be fatal. This is why your doctor should watch you closely, and why it is important for you to tell your doctor immediately if you experience any difficulty in breathing and any skin reactions.

Some patients also have increasing weakness on one side of the body, clumsiness or falls, trouble with thinking or memory, changes in mood, or change in vision. You should report these to your doctor immediately.

If you are receiving RUXIENCE in combination with other medicines, some of the side effects you may experience may be due to the other medicine(s).

For more information on possible side effects of RUXIENCE, please refer to the patient information leaflet provided by your healthcare team.

Talk to your healthcare professional if you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities.



Important safety information

Serious warnings and precautions

Several side effects are associated with RUXIENCE, and some may be severe and life-threatening. This drug should only be used by health professionals experienced in treating rheumatoid arthritis in a setting where medication and supportive care measures are immediately available in the event of an allergic reaction during administration.



Serious infusion reactions can happen during your infusion or within 24 hours after your infusion of RUXIENCE.



Recurrence of hepatitis B virus infection has occurred in patients who show evidence of the virus in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with RUXIENCE.



Serious, including fatal, infections can occur during or following treatment with RUXIENCE. A rare brain infection called JC virus, causing progressive multifocal leukoencephalopathy (PML) and death, has been reported in patients with autoimmune diseases treated with RUXIENCE. It is hard to predict who will get PML, but it is more common in people with weakened immune systems.



Severe skin reactions, such as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported very rarely. Some cases have resulted in death.



Serious and potentially fatal cardiovascular events have been reported rarely following treatment with RUXIENCE.



Preparing for my next appointment

It's important to ask questions and let your healthcare team know if you have any concerns about your treatment. Use the space below to write down anything you would like to bring up with your team at any of your next visits.

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My healthcare team contact information

Name:	Phone number:
Name:	Phone number:
Name:	Phone number:
Name:	Phone number:
Manager	Dhana numban





Support may help

If you think a support group may be helpful to you, ask your healthcare team about support groups in your area.

Additional resources

The Arthritis Research Foundation

Founded in 1998, the Arthritis Research Foundation raises and invests funds for arthritis. In addition, the organization strives to increase awareness of this disease.

Visit www.beatarthritis.ca or call 1-416-586-3224.

Arthritis Research Centre of Canada (ARC)

Arthritis Research Canada is the largest clinical arthritis research centre in North America, and their mission is an aim to transform the lives of people living with arthritis through research and engagement.

Visit www.arthritisresearch.ca or call 1-844-207-0400 (toll-free).

The Arthritis Foundation

The Arthritis Foundation is available to help you navigate the many challenges of arthritis by promoting research, providing disease management support, sharing advocacy opportunities, and creating community connections.

Visit www.arthritis.org or call 1-800-283-7800.

Arthritis Broadcast Network

Led by Arthritis Consumer Experts and Arthritis Research Canada, the Arthritis Broadcast Network (ABN) is a multi-media platform for the arthritis community to share news, information, and stories about their arthritis.

Visit www.arthritisbroadcastnetwork.org.

Joint Health™

Arthritis Consumer Experts (ACE) is a national organization that provides free, science-based information and education programs in both official languages to people with arthritis.

Visit www.jointhealth.org or call 1-604-974-1366.

The suggested resources on this page do not imply an endorsement of or an association with third-party organizations and are provided for information purposes only. Pfizer is not responsible for content of non-Pfizer sites.



Notes	Notes





Patient Support Program

Pfizer**Flex**

Experienced, Dedicated Team

The PfizerFlex Support Program is a personalized service that aims to provide medical, financial, and emotional support throughout your journey. This support program offers information and tips as well as additional resources that can help you during your treatment. Services offered by this support program include:

- Call-centre support with convenient hours of operation where you can reach your PfizerFlex Care Coach for help and questions on enrolment, access to medication, and your treatment plan
- Help with exploring your options for financial assistance
- Information and lifestyle tips to help you manage your RA in the home and workplace
- **Helpful tools** to help you stick with your treatment plan and lead a healthy lifestyle

For more information or to register, call 1-855-935-3539 or visit www.pfizerflex.ca.



For more information, please refer to mypfizer.ca





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