



MORNING SWIM

Redefining MS together

**Get on with life,
we'll see you in 6 months**

Your guide to OCREVUS® (ocrelizumab)

The intent of this patient booklet, developed by Roche Products (New Zealand) Ltd, is to support and improve outcomes for patients prescribed OCREVUS for the treatment of multiple sclerosis.

For more information visit getonwithlife.co.nz

Models have been used throughout this booklet for illustrative purposes only.

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You are receiving this booklet because your healthcare professional has prescribed you a medicine called OCREVUS, also known as ocrelizumab for the treatment of multiple sclerosis. This booklet is an educational resource to help you and your whānau learn more about what to expect from treatment with OCREVUS. It does not take the place of individual advice from your healthcare professional.

More information about OCREVUS is available at getonwithlife.co.nz or in the Consumer Medicines Information at medsafe.govt.nz.

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we'll see you
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For more information visit getonwithlife.co.nz



What is Multiple Sclerosis (MS)?

Multiple sclerosis is a disease that affects the brain, spinal cord and optic nerves, which make up the central nervous system (CNS)

What causes MS?

The exact cause of MS is unknown, but we do know that something triggers the body's immune system to attack the CNS. This damage to the protective layer of insulating nerve fibres (called myelin) disrupts signals to and from the brain. This interruption causes unpredictable symptoms.

Symptoms of MS

Everyone's MS is different since MS can attack different parts of the CNS. You may find it useful to be aware of the possible signs and symptoms of MS. These may be temporary or long lasting.

Tell your doctor or nurse straight away if you think your MS is getting worse or if you notice any new symptoms. Some things to look out for include:

Vision problems

Muscle stiffness

Numbness

Dizziness

Tingling

Pain

Mood changes

Exhaustion

Loss of balance

Memory problems

Pins and needles

Muscle weakness and paralysis

Lack of concentration

Bladder problems

Depression

Bowel problems



About OCREVUS

OCREVUS is a prescription medication for multiple sclerosis



OCREVUS is used to treat relapsing forms of multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS).



OCREVUS is a well-established medicine. More than 450,000 people with MS have been treated globally with OCREVUS over the last 11 years.

OCREVUS leaves you free to get on with life between MS treatments - after the first dose, you'll only need to take it every six months.

OCREVUS is available in two ways:



OCREVUS subcutaneous (SC):
10 minute subcutaneous injection (injection under the skin)*

OR



OCREVUS Intravenous (IV):
2 to 3.5 hour intravenous infusion (slow drip into the vein)*

*This is only administration time and does not account for all aspects of treatment. Actual clinic times may vary. The duration of an infusion may be longer should a reaction occur.

Who is OCREVUS for?

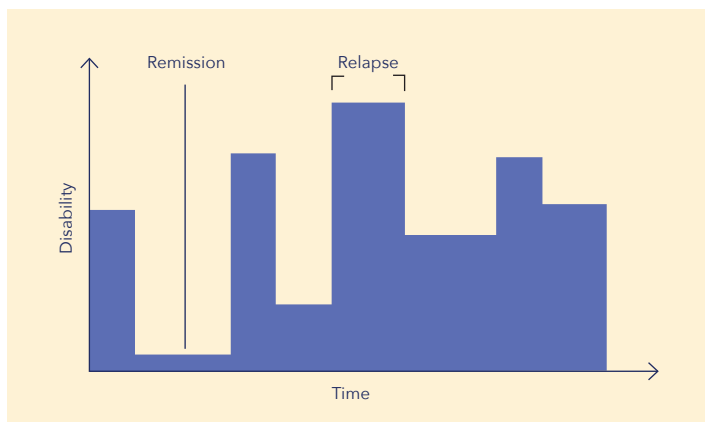
OCREVUS helps with signs and symptoms of Relapsing-Remitting Multiple Sclerosis (RRMS)

Relapses

When a relapse occurs, symptoms may be experienced suddenly, within a few hours, or slowly develop over a few days. As MS progresses, the damage caused by relapses may grow and could lead to permanent disability.

Remission

In people with RRMS, there are periods of full recovery (in which symptoms disappear completely) or partial recovery (in which some symptoms remain).



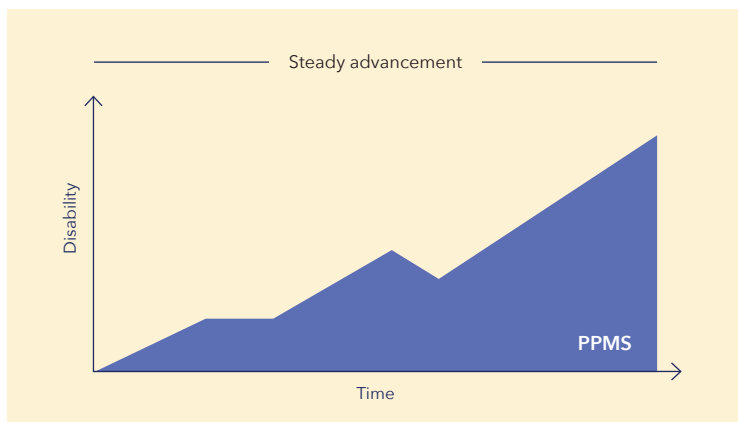
How OCREVUS Reduces Relapses and Slows MS Progression

- Treatment with OCREVUS **reduces the number of relapses** by about half compared with beta-interferon.
- After 11 years of continuous OCREVUS treatment:
 - The average rate of relapses was equivalent to having just **one relapse every 35 years**
 - >3 out of 4 people **remained free of disability progression**
- Starting OCREVUS treatment 2 years earlier could **delay disease progression** by more than 8 years.

OCREVUS helps with signs and symptoms of Primary Progressive Multiple Sclerosis (PPMS)

PPMS advances more steadily than RRMS

Symptoms of PPMS continually get worse from the start of the disease. However, while not typical, some people with PPMS may occasionally experience relapses.



How OCREVUS slows the worsening and overall progression of PPMS

OCREVUS reduces progression of disability:

- After 11 years of continuous treatment with OCREVUS,
 - >1 out of 3 people **remained free of disability progression**
 - Around 8 out of 10 people **did not require wheelchair support**
- Starting OCREVUS treatment 2 years earlier could **delay disease progression** by more than 1.5 years compared with placebo
- OCREVUS **slows down progression of PPMS** and **reduces the deterioration in walking speed** compared with placebo.

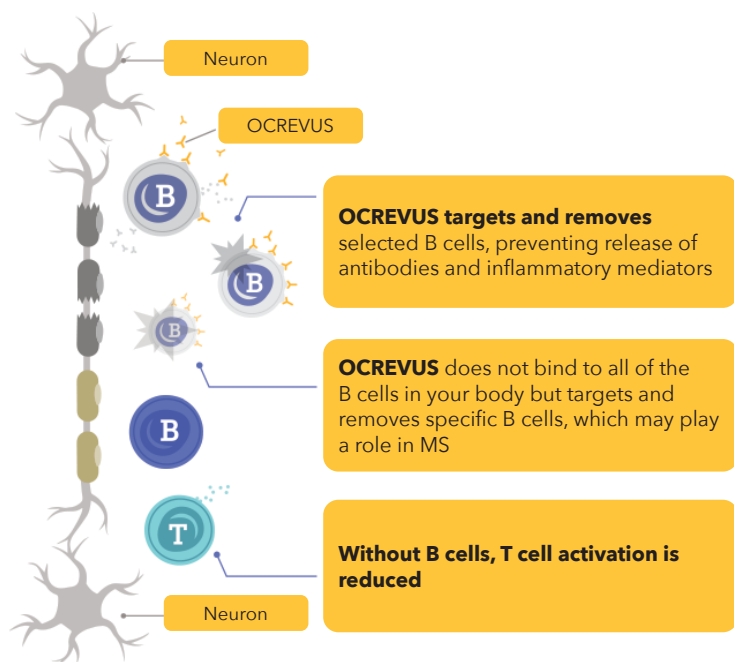
If you would like more information regarding the use of OCREVUS SC for the treatment of MS then please contact the Roche Medical Information team on 0800 276 243 or auckland.medinfo@roche.com

How does OCREVUS work?

Your immune system is made up of lots of different cells that usually all work together to protect your body from possible infections.

In MS, where the immune system attacks the CNS by mistake, there is particular involvement from two types of immune cells called B cells and T cells. These often work together in an immune response.

OCREVUS works on your immune system by targeting and removing specific B cells that play a role in MS. When targeted B cells are removed by OCREVUS, inflammation is reduced, and the risk of other nerve cells becoming infected is also reduced.



Before starting treatment with OCREVUS

There are some side effects and risks to be aware of when taking OCREVUS. Your doctor will consider the best time for you to begin treatment with OCREVUS.

Do not use OCREVUS if:

- You have had an allergic reaction to OCREVUS or any of its ingredients.
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash and/or itching or hives on the skin.

Before you receive OCREVUS, tell your doctor if:

- You have an infection, or a history of recurring or long-term infection (such as hepatitis B).
If you are taking or have taken medicines which affect your immune system, you may have an increased risk of infections.
- You are taking or have previously taken medicines which may affect your immune system, such as medicines for MS.
- You or your child intend to have or have had immunisation with any vaccine.
- 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.
Avoid the use of OCREVUS during the second and third trimester of pregnancy, unless advised otherwise by your doctor.
- You are breastfeeding, or plan to breastfeed.
Avoid breastfeeding for the first few days after birth while you are using OCREVUS.

Things to remember before your OCREVUS treatment

Allow yourself enough time



- Ask your MS nurse when you should arrive for your OCREVUS treatment. Your MS team may want to carry out some checks on your health and wellbeing, before they give you OCREVUS
- Allowing yourself enough time – before, during and after your appointment – can help reduce any stress you may be having about your treatment

Take your pre-medication



- Before you receive OCREVUS, you will be given some other medicines (called pre-medications) to control possible side effects or reactions to OCREVUS
- If you are due to receive OCREVUS SC, you may be asked to take the pre-medication as tablets at home



Please talk to your MS nurse, who can advise you when to take your pre-medication

Plan your journey



- The pre-medication you receive before your OCREVUS treatment might make you feel sleepy
- You may want to ask someone to drive you to your OCREVUS appointment or book a taxi in advance

Tell your MS team about your health



- Before each OCREVUS treatment, tell your MS team if you are taking any new medication, if you may be pregnant, or if you are feeling unwell
- They will advise you on how to manage these conditions, and may reschedule your OCREVUS clinical appointment, if needed

Eat and drink, as normal



- You can eat as usual before your OCREVUS treatment
- Make sure you stay hydrated before your OCREVUS treatment by drinking plenty of water
- This can also help boost your overall wellbeing
- There are no known interactions between OCREVUS and alcohol. However, drinking alcohol before OCREVUS treatment is not recommended as alcohol dehydrates your body

Keep up your daily activities



- Besides taking off time for your OCREVUS treatment, you can engage in your daily activities, physical activities, and exercise as normal

How is OCREVUS given?

OCREVUS can be given in two ways:

- As an intravenous infusion into the vein (OCREVUS IV treatment)
- As a subcutaneous injection under the skin of the abdomen (OCREVUS SC treatment)

You will have discussed and decided with your MS team what the best OCREVUS treatment option is for you. In both cases, OCREVUS needs to be administered by someone from your MS team.

Dosing schedules for OCREVUS

Different ways of administering OCREVUS		
Treatment type	 OCREVUS SC Injection:	 OCREVUS IV Infusion:
Doses per year	2 doses per year One single 920mg dose every 6 months	2 doses per year The first dose is split into two 300 mg treatment infusions, 2 weeks apart Further doses are administered as one 600 mg infusion, every 6 months
Administration method	A subcutaneous injection under the skin, in your abdomen area	An intravenous infusion, into a vein in your arm
Pre-medication requirements	To be taken usually as tablets you can swallow shortly before each injection.	To be given via IV around 30-60 minutes before each infusion
Treatment administration time	Around 10 minutes	Around 2 to 3.5 hours Depending on how you respond to the first dose or subsequent doses, your doctor may recommend a shorter or longer infusion time
Given by	A healthcare professional	A healthcare professional
Monitoring requirements	After your first injection, your MS team will watch you for at least an hour to make sure you're doing okay; for future doses, your doctor will decide how long you need to be monitored	You will be monitored for at least one hour after your infusion is complete to check for any signs of side effects

What happens at an OCREVUS SC administration appointment?

Treatment Stages	For OCREVUS SC injection:	
Check-in	A nurse will run through a checklist with you to make sure everything is OK before the injection	
Pre-medication	• You will take pre-medication shortly before starting your OCREVUS SC treatment, usually as tablets you will swallow • Your doctor may give you the option to take your pre-medication at home before arriving at your OCREVUS SC treatment appointment	
Injection time	Around 10 minutes	
Starting the injection	• You will be asked to sit or lay down, and a thin needle will be inserted under the skin, in your abdomen area. This needle will be connected to the prepared syringe containing OCREVUS SC • The nurse will either inject OCREVUS SC manually, or will use an automatic pump to do this	
Monitoring after treatment	• After your first injection, your healthcare team will ask you to stay for at least an hour so they can watch for any side effects. • You should also keep an eye out for any signs of a reaction for up to 24 hours after your treatment. • Please refer to page 15 for a list of possible side effects to look out for.	
Discharge	• Before leaving, you will receive contact details for your clinic, in case you need to get in touch with your MS team • Your MS team will also schedule your next OCREVUS SC administration appointment	

How much total time will my OCREVUS appointment take?

For OCREVUS SC treatment:

Your OCREVUS SC administration appointment may take from around 20 minutes to 2.5 hours

Allow around 2.5 hours for your first visit. This will include:

- If you are given pre-medication at the clinic, you will receive it shortly before your injection. (If you take pre-medication at home, you will not need this time at the clinic)
- 10-15 minutes for check-in and the injection administration
- At least 1 hour of monitoring by your MS team to watch out for any reactions after your first injection

During subsequent visits, your total OCREVUS SC appointment time may be just **10-15 minutes**, if you have had no reactions to your first injection.

For OCREVUS IV treatment:

In total, your OCREVUS IV administration appointment may take from around 4 to 5.5 hours. This will include:

- 10 minutes check-in and 30-60 minutes for pre-medication
- 2 hours or 3.5 hours for the IV infusions (the first 2 infusions will each last 2.5 hours)
- At least 1 hour of monitoring by your MS team after your infusion

Important information on OCREVUS

What are the possible side effects of OCREVUS treatment?

There are some side effects and risks to be aware of when receiving OCREVUS, whether through IV infusion or SC injection. Your healthcare provider will consider the best time for you to begin treatment with OCREVUS.

While receiving OCREVUS SC, you may experience **injection reactions (IRs)**, which are most common with your very first dose. These reactions usually happen during the injection or within the next 24 hours. IR symptoms are typically mild to moderate, usually resolve within a few days, and are limited to the spot where you were injected—including things like:

- redness
- swelling
- itching
- pain

Occasionally, you might feel more general symptoms like a headache, nausea, or flushing.

For OCREVUS IV infusion, the most common side effects are **infusion-related reactions (IRR)**. IRRs can be serious, so you'll be carefully monitored throughout your infusion and for at least one hour afterwards. However, because IRRs can happen for up to 24 hours after a dose of OCREVUS IV, it is important that you tell your doctor or go to the Accident and Emergency at your nearest hospital if you notice any of the following:

- itchy skin, rash, hives, redness of the skin
- throat irritation or pain
- shortness of breath
- swelling of the throat, face, lips, tongue, or other parts of the body
- redness on your face (flushing)
- low blood pressure
- fever
- fatigue
- nausea
- headache
- fast heartbeat

Managing side effects

Both OCREVUS IV and OCREVUS SC increase your risk of getting upper respiratory and lower respiratory tract infections, skin infections, and herpes infections.

Tell your healthcare provider if you have an infection or have any of the following signs of infection including:

- fever
 - chills
 - a cough that does not go away
 - signs of herpes (such as cold sores, shingles, or genital sores).
 - COVID-19 or COVID-19 pneumonia
-

Rare cases of liver injury have been reported after treatment with OCREVUS. Tell your doctor straight away if you notice any signs of liver problems such as:

- new or worsening fatigue
 - loss of appetite
 - nausea
 - vomiting
 - pain in the right part of your abdomen
 - dark-colored urine
 - yellowing of your skin or eyes
-

There have been reports of a rare, serious brain infection called PML (progressive multifocal leukoencephalopathy) in patients receiving medicines for MS. PML can occur in patients taking OCREVUS (both IV and SC formulations) and is mostly associated with risk factors, such as age and pre-existing use of immunosuppressants. PML can cause severe disability or even death. Symptoms of PML can be similar to those of MS.

Tell your partner or carer about your OCREVUS treatment. They might notice symptoms that you do not, such as changes in movement or behaviour, which your doctor may need to investigate.

Scheduling an appointment for your next dose



OCREVUS is administered every 6 months. It is important to **stick to this dosing schedule** to ensure that OCREVUS is safe and effective.

Your MS team will usually schedule an appointment for your next OCREVUS administration, after you receive each OCREVUS treatment.

If you are not aware of the details of your next dose, reach out to your MS team to schedule an appointment for this.

Managing your MS treatment

Remember that OCREVUS treatment administration is just one part of your MS management.

Your doctor or other members of the MS team might ask you to come in regularly for check-ups or scans.

These will help them to assess your MS, and see if your treatment is working effectively and safely.



Frequently asked questions

I am currently receiving OCREVUS IV. Can I switch to the SC injection?

Yes, switching from the IV infusion to the SC injection is an option for many patients. If you are interested in switching, you should discuss it with your MS team. They can help you decide if it's the right choice for your individual situation and explain the process. Typically, you would receive your first SC injection at the time your next IV infusion would have been scheduled.

Will OCREVUS SC work as well as OCREVUS IV?

Yes. In a clinical trial involving patients with either RRMS or PPMS, the OCREVUS SC injection was found to be comparable to the IV formulation in terms of safety and effectiveness.

What if I have a reaction to my OCREVUS treatment?

You should always tell your doctor or nurse if you experience any side effects during or after your treatment so that they can support you and provide advice.



Remember though, if you need travel vaccines for your holiday, you should arrange to have these **at least 6 weeks** before you start your next treatment with OCREVUS.

While you are being treated with OCREVUS, you **should NOT** be given live or live attenuated vaccines. Always check with your MS team before arranging any travel or seasonal vaccines.

What happens if I miss a dose?

Please do not make any decisions on changing your treatment plan without consulting your MS team first. If you are not able to take your treatment for personal reasons, please inform your MS team. They are there to advise you on how to proceed in these situations.



If you have missed an appointment, please reach out to your MS team to schedule an alternative appointment **as soon as possible – do not wait** until the next planned dose.

It is important to stick to OCREVUS, as prescribed by your doctor, to ensure your MS is controlled in the best way.

OCREVUS should be administered every 6 months (with a minimum interval of 5 months between each dose).

How do I know that OCREVUS is working?

OCREVUS probably won't make you feel 'better'. Its aim is to reduce the level of activity of your MS, including the likelihood of a relapse, and to slow down the progression of your MS.

OCREVUS does not directly treat your MS symptoms (like fatigue). Your doctor will regularly assess if your treatment is working by checking:

- If and how many relapses you have had
- How severe the relapses were
- The number of lesions seen on your medical scans
- Changes in your physical and mental abilities

Appointment diary

Some people with MS use a diary to note down their next treatment appointment details, and to record any healthcare changes they may notice between their appointments.

Visit 1
Date: _____
Time: _____

Visit 2
Date: _____
Time: _____

Visit 3
Date: _____
Time: _____

Visit 4
Date: _____
Time: _____

Things to discuss with your MS team

You can add your own thoughts and questions here,
for your own benefit or to discuss with your MS team.

[illegible]

Your clinic's contact details

You or your MS team can fill in these important contact details, so you can keep them handy.

Clinic Name:

Nurse/Doctor Name:

Clinic Address:

Clinic Email/Telephone:

Glossary

- **Antibody:** A protein produced by certain cells of the immune system. It is produced in response to bacteria, viruses, and other types of foreign antigens.
- **B-Cell:** A type of lymphocyte (white blood cell) made in the bone marrow that makes antibodies.
- **Beta-interferon:** Is an anti-inflammatory medication that acts to reduce the inflammation and the immune response from attacking the body's own myelin.
- **Central Nervous System (CNS):** The part of the nervous system that includes the brain, optic (visual) nerves, and spinal cord.
- **Immune system:** A complex network of glands, tissues, circulating cells, and processes that protect the body by identifying abnormal or foreign substances and neutralising them.
- **Injection Reactions (IR):** Some possible symptoms may include redness, pain, swelling, or itchiness at the injection site.
- **Infusion-Related Reactions (IRR):** Some possible symptoms are itchiness, rash, throat irritation, flushing, and headache.
- **Intravenous (IV) infusion:** Delivery of medicine by slow injection into the vein (slow drip over hours).
- **Magnetic Resonance Imaging (MRI):** A tool that uses magnetic energy and radio waves to take pictures of the inside of your body, including areas like your brain or spine.
- **Myelin:** The protective coating that insulates nerves allowing nerve signals to travel quickly.
- **Neuron:** The basic nerve cell of the nervous system.
- **Placebo:** A substance with no active therapeutic effect.
- **PML:** Progressive Multifocal Leukoencephalopathy is a rare and serious brain infection.
- **Primary Progressive Multiple Sclerosis (PPMS):** Primary progressive multiple sclerosis is a less common form of multiple sclerosis. People with PPMS usually have progressive worsening of neurologic function or accumulation of disability from the start.
- **Relapsing-Remitting Multiple Sclerosis (RRMS):** The most common form of multiple sclerosis where there are clear attacks of new or worsening symptoms, also known as relapses. These relapses are followed by periods of partial or complete recovery, called remission.
- **Subcutaneous (SC):** Delivery of medicine by injection, under the skin in the stomach area, within minutes.
- **T-Cell:** A lymphocyte (white blood cell) that develops in the bone marrow, matures in the thymus, and works as part of the immune system in the body.

Ocrevus® IV (ocrelizumab) 300mg vial, and **Ocrevus® SC** (ocrelizumab 920 mg/23 mL solution for subcutaneous injection) are **Prescription Medicines** used to treat relapsing forms of multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS).

Ask your doctor if Ocrevus is right for you.

Ocrevus IV when given as an infusion into the vein and Ocrevus SC when given as an injection under the skin, are funded medicines for patients who meet defined criteria.

Ask your health professional about the cost of the medicine and other fees that may apply.

Use only as directed. If symptoms continue or you have side effects, see your healthcare professional. For more information about Ocrevus:

- talk to your health professional; or
- visit medsafe.govt.nz for Ocrevus Consumer Medicine Information; or
- visit getonwithlife.co.nz or call Roche on 0800 276 243.

Ocrevus has risks and benefits.

Possible common side effects include: ***Infusion-related reactions and injections reactions:*** symptoms can include itchiness, rash, hives or redness of the skin; throat irritation or pain; shortness of breath; swelling of the throat, face, lips, tongue, or other parts of the body; reactions in the area where the injection is given (Ocrevus SC only); redness on your face (flushing); low blood pressure; fever; fatigue; nausea; headache; fast heart beat ***Infections:*** viral infections (influenza, COVID-19); respiratory tract infections (runny nose, sneezing, sore throat, cough, fever, fatigue, weakness, shortness of breath); inflammation or infection of the sinuses - sinusitis (feeling of pressure or pain in the cheeks and forehead); inflammation or infection of the lung - bronchitis (cough, chest pain, fever); build-up of mucus in the nose and throat; infection of the stomach and bowel - gastroenteritis (nausea, vomiting, fever); eye inflammation or infection - conjunctivitis (itchy, red or sore eyes); or skin infection - cellulitis (rash, itching or hives on the skin).

Do not use Ocrevus if: you have had an allergic reaction to Ocrevus or any of the ingredients.

Tell your doctor if: have any signs and symptoms of infection, or a history of a recurring or long-term infection such as hepatitis B; you are taking or have taken medicines which affect your immune system; you or your child intend to have or have had immunisation with any vaccine; you are allergic to any other medicines or any other substances such as foods, preservatives or dyes; have any other medical conditions; you take any medicines for any other condition (including those for MS, or to treat other conditions and medicines that lower blood pressure); 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; you have any new medical conditions or plan to take any new medicines for any other condition; you have signs and symptoms that may indicate a liver problem **Pregnancy:** tell your doctor if you are pregnant or plan to become pregnant. You should avoid using Ocrevus during the second and third trimester of pregnancy, unless advised otherwise by your doctor. **Breastfeeding:** Talk to your doctor if you are breastfeeding or plan to breastfeed. You should avoid breastfeeding for the first few days after birth while you are using Ocrevus

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following: ***Infusion-related reactions, injections reactions, or allergic reactions:*** symptoms can include itchy skin, rash, hives or redness of the skin; throat irritation or pain; shortness of breath; swelling of the throat, face, lips, tongue, or other parts of the body; reactions in the area where the injection is given (Ocrevus SC only); redness on your face (flushing); low blood pressure; fever; fatigue; nausea; headache; fast heart beat ***Infections:*** symptoms such as fever or chills; cough that does not go away; herpes (such as cold sore, shingles and genital sores); COVID-19 pneumonia ***Progressive multifocal leukoencephalopathy (PML):*** think your multiple sclerosis is getting worse or if you or your partner or caregiver notice any new or unusual symptoms such as changes in movement or behaviour. There have been very rare reports of serious brain infection, called PML in patients receiving medicines for MS, which can cause severe disability or be life-threatening. Symptoms of PML can be similar to those of MS. ***Liver problems:*** symptoms such as new or worsening fatigue; loss of appetite; nausea; vomiting; pain in the right part of your abdomen; dark-coloured urine; yellowing of your skin or eyes

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M-NZ-00001400-v3/DA2521KS/JUL2026

