Ocrevus®

Ocrevus intravenous (IV): ocrelizumab 300 mg in 10 mL concentrate for solution for infusion
Ocrevus subcutaneous (SC): ocrelizumab 920 mg in 23 mL solution for subcutaneous injection

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.

1. Why am I using Ocrevus?

Ocrevus contains the active ingredient ocrelizumab. Ocrevus is used for the treatment of patients with relapsing forms of multiple sclerosis and primary progressive multiple sclerosis. For more information, see Section 1. Why am I using Ocrevus? in the full CMI.

2. What should I know before I use Ocrevus?

Do not use if you have ever had an allergic reaction to Ocrevus 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 Ocrevus? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ocrevus and affect how it works or Ocrevus may affect how other medicines work. 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 Ocrevus?

Your doctor or nurse will administer your Ocrevus dose as an intravenous infusion, or as a subcutaneous injection. More information can be found in Section 4. How do I use Ocrevus? in the full CMI.

5. What should I know while using Ocrevus?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Ocrevus. • Tell your doctor or nurse if you have any signs and symptoms of infection; any signs or symptoms of infusion or injection related reaction or allergic reaction; any stomach or bowel problems; or any signs or symptoms of a liver problem. • Tell your doctor if you plan to receive or have received a vaccine. • Use contraception during treatment with Ocrevus and for at least 4 months after your last dose. • Avoid the use of Ocrevus during pregnancy unless advised otherwise by your doctor. • Talk to your doctor if you are breastfeeding or intend to breastfeed. • Tell your doctor immediately if your condition worsens, or if you, your partner or caregiver notice any new symptoms like changes in movement or behaviour.
Things you should not do	• Do not stop using this medicine without talking to your doctor first.
Driving or using machines	• It is not known if Ocrevus will influence your ability to drive or use machines.
Looking after your medicine	• It is unlikely that you will have to store Ocrevus at home. If necessary, refrigerate between 2°C and 8°C, do not freeze. • Keep the vial in the carton to protect it from light and keep it out of reach of children.

For more information, see Section 5. What should I know while using Ocrevus? in the full CMI.

6. Are there any side effects?

Common side effects include infusion related reactions or injection reactions and some types of infections, which can be serious or less serious. Allergic reactions (swelling of the face, lips, tongue or throat, trouble breathing, chest tightness, wheezing, coughing, and asthma that becomes worse) are serious side effects. Stomach and bowel problems (diarrhoea that does not go away, stomach pain, or blood in your stools) or liver problems (new or worsening fatigue, loss of appetite, nausea, vomiting, pain in the right part of the abdomen, dark-colored urine, or yellowing of your skin or eyes) could be a serious side effect. 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.

Ocrevus® (pronounced oak-rev-us)

Active ingredient: *ocrelizumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ocrevus. **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 Ocrevus.**

Where to find information in this leaflet:

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

1. Why am I using Ocrevus?

Ocrevus contains the active ingredient ocrelizumab. Ocrevus is a monoclonal antibody. Antibodies are proteins, produced naturally in the body, which help the immune system by specifically recognising and binding to proteins found on target cells. Monoclonal antibodies are designed and manufactured to work like natural antibodies so that they can target specific proteins involved in disease.

Ocrevus is used to treat patients with relapsing forms of multiple sclerosis (MS) and primary progressive multiple sclerosis.

Ocrevus works on cells of the immune system called B-cells, which play a role in multiple sclerosis. By targeting specific B cells, Ocrevus may reduce inflammation and attacks to the nervous system. Ocrevus can decrease the number of flare-ups (relapses) and slow the worsening of relapsing forms of multiple sclerosis. It can also reduce the worsening of primary progressive multiple sclerosis.

2. What should I know before I use Ocrevus?

Warnings

Do not use Ocrevus if:

- you are allergic to ocrelizumab, or any of the ingredients listed at the end of this leaflet.
- you have an active infection.
- you have a severely weakened immune system (severe immunocompromised state).
- you have any type of cancer.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any signs and symptoms of infection. You should not have your treatment until the infection is resolved.
- have ever had hepatitis B or are a carrier of the hepatitis B virus. Before you start using Ocrevus, your doctor will check if you have or are at risk of having hepatitis B infection to decide if you can use Ocrevus and if they may need to monitor you during your treatment with Ocrevus.
- have, or have ever had, cancer. Some type of medicines that work on the immune system may increase the risk of some cancers.
- intend to have or have had immunisation with any vaccine. Some types of vaccines (called 'live' or 'live-attenuated') should not be given at the same time as Ocrevus and in the months after you receive Ocrevus. Your doctor will check if you should have any vaccines before you receive Ocrevus. Ocrevus may affect your normal response to a vaccine.
- are allergic to any other medicines or substances.
- have any other medical conditions.
- take any medicines for any other condition.

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

Tell your doctor if you are pregnant or intend to become pregnant.

You should use effective contraception during treatment with Ocrevus if there is a potential for pregnancy and for at least 4 months after your last dose of Ocrevus.

You should avoid using Ocrevus during pregnancy, unless advised otherwise by your doctor.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. If you are breastfeeding, you can use Ocrevus starting a few days after birth.

Breast milk may have a small amount of Ocrevus. A study has shown that babies had normal growth and development for up to 1 year. However, the long-term effects are still unknown

Children and Adolescents

It is not known whether Ocrevus is safe or effective in children and adolescents under 18 years of age, because it has not yet 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.

Ocrevus may affect how some medicines work:

- vaccines. Speak to your doctor before you receive any vaccines. You should not have some types of vaccines (called 'live' or 'live-attenuated') while receiving Ocrevus and for several months after until your doctor advises that you can.

These medicines increase your risk of side effects with Ocrevus:

- other treatments (including those for MS, or to treat other conditions) which could affect your immune system and so could affect your ability to fight infections. If you are currently using a different MS treatment or if you have used another MS treatment in the past, your doctor may ask you to stop the other medicine in advance of starting treatment with Ocrevus.
- medicines that lower blood pressure. Ocrevus may lower your blood pressure. Your doctor may ask you to temporarily stop taking your blood pressure medicine before each dose.

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

4. How do I use Ocrevus?

How much to use

Ocrevus intravenous (IV)

Ocrevus IV must be prepared by a healthcare professional and will be given in a hospital or clinic. You will have Ocrevus as an intravenous infusion. It will go slowly into your vein. This will be done by your doctor or nurse.

Before you receive Ocrevus, your doctor or nurse will give you other medicines to help reduce possible side effects such as infusion-related reactions.

- The dose is 600 mg every 6 months.
- Your first 600 mg will be given as 2 separate intravenous infusions (300 mg each), given 2 weeks apart by a doctor or nurse. Each infusion will take about 2 hours and 30 minutes.
- Your next 600 mg doses of Ocrevus will be given as a single intravenous infusion every 6 months. These infusions will take either about 2 hours or 3 hours and 30 minutes depending on the infusion rate prescribed by your doctor.
- Your doctor or nurse will closely monitor you during each infusion and may adjust your infusion rate depending on how well each dose is tolerated.
- Follow the instructions provided and use Ocrevus until your doctor tells you to stop.

Ocrevus subcutaneous (SC)

Ocrevus SC must be administered under the supervision of a healthcare professional.

Before you receive Ocrevus you will be given other medicines to help reduce the risk of possible injection reactions.

- The first injection: you will be given 920 mg of Ocrevus by SC injection in approximately 10 minutes. You will be closely monitored for at least one hour after the first injection to manage any possible injection reactions.
- Subsequent injections: if the previous injection was well tolerated, you will be given 920 mg of Ocrevus by SC injection 6 months after the previous injection.

If you miss your dose

If you forget or miss your appointment for your treatment, do not wait until the next planned dose but make another appointment as soon as possible. Your doctor may need to change the timing of your later doses.

If you use too much Ocrevus

Your dose of Ocrevus is given to you by infusion or injection under the supervision of a doctor or nurse. However, if you think that you have received too much Ocrevus, you may need urgent medical care.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 Ocrevus?

Things you should do

- Tell your partner or caregiver 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.
- If you plan to become pregnant or you become pregnant during treatment with Ocrevus, tell the doctor right away. Tell your baby's doctor about your treatment with Ocrevus so that they can consider this in the timing of your baby's vaccinations.
- Tell your doctor if you have any signs and symptoms of infection even if it has been some time (e.g. several weeks or months) since your last dose. Your doctor may need to do a blood test to check your white blood cell levels.
- Tell your doctor if you have any stomach or bowel problems such as diarrhoea that does not go away, stomach pain, or blood in your stools.
- Tell your doctor if you have signs and symptoms that may indicate a liver problem (e.g. new or worsening fatigue, loss of appetite, nausea, vomiting, pain in the right part of your abdomen, dark-colored urine, or yellowing of your skin or eyes). Your doctor will order a blood test to check your liver.
- Tell your doctor if you have any new medical conditions or plan to take any new medicines for any other condition.

Call your doctor straight away if you:

- have any signs or symptoms of infusion or injection related reactions or allergic reactions.
- 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 progressive multifocal leukoencephalopathy (PML) which can cause severe disability or be life-threatening. Symptoms of PML can be similar to those of MS.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using Ocrevus.

Things you should not do

- Do not stop using this medicine without talking to your doctor first.
- 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 Ocrevus affects you.

It is not known whether Ocrevus can affect you being able to drive or use any tools or machines.

Looking after your medicine

- It is unlikely that you will have to store Ocrevus at home. If you have to store it: refrigerate, do not freeze. Store between 2°C and 8°C. Do not shake it.
- Keep the vial in the carton to protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

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 likely to be 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
Infections such as: • viral infection (such as, but not limited to, influenza) • respiratory tract infection (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 or vomiting, fever) • eye inflammation or infection - conjunctivitis (itchy, red or sore eyes) • skin infection - cellulitis (rash, itching or hives on the skin)	**Tell your doctor or nurse straight away if you have any of these side effects, even if it has been sometime since your last infusion or injection. These side effects can sometimes be serious.** If you experience signs and symptoms of infection, your doctor may need to do a blood test to check your white blood cell levels even if it has been some time (e.g. several weeks or months) since your last infusion or injection.

Serious side effects

Serious side effects	What to do
Infusion related reactions, injection reactions or allergic reactions: Infusion related reactions or injection reactions can happen during the infusion and within 24 hours after the infusion or injection. Symptoms may include, but are not limited to: • 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 • reactions in the area where the injection is given (Ocrevus SC only) • redness on your face (flushing) • low blood pressure • fever	**During your infusion or injection, tell your doctor or nurse straight away if you experience signs and symptoms of infusion related reactions or injection reactions.** **After your infusion or injection, call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects. These may be serious side effects.**

Serious side effects	What to do
• fatigue • nausea • headache • fast heart beat **Infections and signs or symptoms such as:** • fever or chills • cough that does not go away • herpes (such as cold sore, shingles and genital sores) • pneumonia • mouth ulcers/sore throat • rashes • swelling or pain around a wound • feeling tired **Stomach and bowel problems such as:** • diarrhoea that doesn't go away • stomach pain • blood in your stools • **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 **Lowered immune response:** Low white blood cell count leading to increased risk of infections such as bacterial and fungal infections. **Lung related issues such as:** Inflammation and scarring of lung tissue due to long term damage to the lungs, known as interstitial lung disease. Symptoms can include: • feeling short of breath • dry cough • feeling discomfort in the general chest area	**Tell your doctor straight away if you have any of these side effects, even if it has been sometime since your last infusion or injection.**

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. 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 Ocrevus IV contains

Active ingredient (main ingredient)	Each vial of Ocrevus IV contains 300 mg of ocrelizumab
Other ingredients (inactive ingredients)	sodium acetate trihydrate trehalose dihydrate acetic acid polysorbate 20 water for injections

What Ocrevus SC contains

Active ingredient (main ingredient)	Each vial of Ocrevus SC contains 920 mg of ocrelizumab
Other ingredients (inactive ingredients)	vorhyaluronidase alfa sodium acetate trihydrate trehalose dihydrate acetic acid polysorbate 20 methionine water for injections

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

What Ocrevus IV looks like

Ocrevus IV is registered on the ARTG as AUST R 275778.

Ocrevus IV is supplied as a single-dose glass vial containing 10 mL of solution for intravenous infusion (30 mg/mL). Ocrevus is diluted before infusion into a vein.

Ocrevus IV is a clear or slightly opalescent, and colourless to pale brown liquid.

What Ocrevus SC looks like

Ocrevus SC is registered on the ARTG as AUST R 446150.

Ocrevus SC is supplied as a single-dose glass vial containing 23 mL of solution for subcutaneous injection (40 mg/mL).

Ocrevus SC is a clear or slightly opalescent, and colourless to pale brown liquid.

Who distributes Ocrevus

Ocrevus is supplied in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

Australia

Website: www.roche-australia.com/ or www.medinfo.roche.com accessible by scanning the below QR code:

This leaflet is for people in Australia only. If you are not in Australia, you can contact Roche/Genentech in your country at www.medinfo.roche.com.

This leaflet was prepared in November 2026.