PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Ocrevus®; concentrate for solution for infusion

The active substance is ocrelizumab

Sugar free

Read all of this leaflet carefully before you start taking Ocrevus

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.

What is in this leaflet

1. What Ocrevus is and what it is used for
2. What you need to know before you are given Ocrevus
3. How you are given Ocrevus
4. Possible side effects
5. How to store Ocrevus
6. Contents of the pack and other information

1. What Ocrevus is and what it is used for

Ocrevus contains the active substance ocrelizumab, which is a type of a protein called a monoclonal antibody.

Ocrevus is used to treat your multiple sclerosis (MS) if you have symptoms that continuously get worse from the start of the disease or if you are having repeated attacks or symptoms (relapses).

In primary progressive multiple sclerosis (PPMS) Ocrevus helps to slow down the progression of the disease and reduce deterioration in walking speed.

How Ocrevus works

Ocrevus attaches to specific B cells, which are a type of white blood cells that are part of the immune system and play a role in MS. Ocrevus targets and removes those specific B cells. This reduces inflammation and attacks on the myelin sheath, reduces the chance of having a relapse and slows the progression of your disease.

2. What you need to know before Ocrevus is administered to you

You should not be administered Ocrevus:

If you are hypersensitive (allergic) to ocrelizumab, or to any of the other ingredients of Ocrevus.

If you have a life threatening reaction to an Ocrevus infusion.

If you have an active hepatitis B virus infection or an active hepatitis C virus infection.

If you have an infection of any kind, including active tuberculosis, at the time when you are due to receive your Ocrevus infusion.

You must not receive vaccines that are known as live attenuated vaccines.

- If you are a woman and are able to fall pregnant, you should use contraception while receiving Ocrevus and for 6 months after your last infusion of Ocrevus.

Warnings and precautions

Tell your doctor or healthcare professional before being given Ocrevus infusion if:

- **You think your MS is getting worse or if you notice any new symptoms**. This is because of a very rare and life-threatening brain infection, called 'Progressive Multifocal Leukoencephalopathy' or 'PML', which can cause symptoms similar to those of MS. PML can occur in patients taking medicines like Ocrevus. The reporting rate with OCREVUS has been approximately 1 case per 100,000 patients
- Tell your partner or carer about your Ocrevus treatment. They might notice symptoms that you do not, such as memory lapses, troubles thinking, difficulty walking, sight loss, changes in the way you talk, which your doctor may need to investigate.
- You think you have an **infection**. Your doctor will wait until the infection is resolved before administering Ocrevus to you.
- You have ever had a type of liver disease called **hepatitis B** or are a carrier of the hepatitis B virus. This is because Ocrevus type medicines can cause the hepatitis B virus to become active again. Before your Ocrevus treatment, your doctor will check if you are at risk of having hepatitis B infection. Patients who have had hepatitis B or are carriers of the hepatitis B virus will have a blood test and will be monitored by a doctor for signs of hepatitis B infection. This is because the virus could become active and may result in serious liver problems.
- Tell your doctor or nurse straight away if you experience any signs or symptoms of an **infusion-related or hypersensitivity reaction**. Infusion-related reactions are the most common side effect of Ocrevus- treatment and may present as itchy skin, rash, hives, red inflamed skin, throat irritation, ear and throat pain, difficulty in breathing, accumulation of fluid in your throat or voice box (larynx), flushing, low blood pressure, fever, fatigue, headache, dizziness, nausea, rapid beating of your

heart and anaphylaxis (an acute hypersensitivity reaction). Infusion related reactions can happen during the infusion or up to 24 hours after the infusion.

To reduce the risk of infusion-related reaction, your doctor will give you other medicines before each infusion of Ocrevus (see "How Ocrevus is given") and you will be closely monitored during the infusion and for at least one hour after the infusion has been given.

- You might get **infections** more easily with Ocrevus. This is because the immune cells that Ocrevus targets may help to fight infection.

Tell your doctor or nurse straight away if you have any of these signs of infection during or after Ocrevus treatment:

- fever and/or chills
- cough which does not go away
- herpes (such as cold sore, shingles or genital sores).

Vaccinations

Tell your doctor if you have recently been given, or might be given in the near future, any sort of vaccine. While you are being treated with Ocrevus, you should not be given some types of vaccine, called 'live' or 'live attenuated' vaccines (for example BCG (Bacille Calmette-Guerin) for tuberculosis or vaccines against yellow fever). In addition to not having live or live-attenuated vaccines during your Ocrevus treatment, it is also not known how Ocrevus may affect your response to other types of vaccines.
Your doctor will check if you need any vaccinations before you start treatment with Ocrevus. Any vaccinations should be given at least 6 weeks before you start treatment with Ocrevus.

Use in children and adolescents

Ocrevus is not recommended for anyone under the age of 18 years

Other medicines and Ocrevus

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if:

- You have ever taken, are taking or are planning to take **medicines which affect your immune system** - such as chemotherapy, immuno-suppressants or other treatments for MS. These medicines could affect your ability to fight infections in combination with Ocrevus.
- You are taking **medicines for high blood pressure**. This is because some people have a decrease in their blood pressure while being given Ocrevus. Your doctor may ask you to stop taking these medicines for 12 hours before each Ocrevus infusion.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given Ocrevus.

Pregnancy, Breastfeeding and Fertility

Pregnancy

Do not use Ocrevus if you are pregnant. Your doctor will not give you Ocrevus if you are pregnant due to the possible risk to your baby.

Tell your doctor before being administered Ocrevus if you are pregnant, if you think you are pregnant or if you are planning to have a baby. This is because Ocrevus may cross the placenta and affect your baby.

Talk to your doctor before vaccinating your baby.

Contraception for women

If you are able to become pregnant (conceive), you must use contraception during treatment with Ocrevus and for 6 months after your last infusion of Ocrevus.

Breastfeeding

Do not breastfeed your baby while you are being treated with Ocrevus. This is because Ocrevus will pass into breast milk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being given Ocrevus

Interference with daily activities

You may still be getting reactions to your infusion for up to 24 hours after your infusion which may impair your ability to drive or to use machines. For signs and symptoms of infusion reactions, see "Warnings and precautions" above.

3. How Ocrevus is given

Ocrevus will be given to you by a doctor or a nurse. It will be given as an infusion into a vein (called an intravenous infusion or 'IV' infusion).

You will be closely monitored while you are being given Ocrevus and for at least 1 hour after the infusion has been given. This is in case you experience any side effects such as infusion related reactions. The infusion may be slowed, temporarily stopped or permanently stopped if you have an infusion-related reaction, depending on how serious it is.

Medicines you will have before you are given Ocrevus

Before you are given Ocrevus, you will receive other medicines to prevent or reduce possible side effects such as infusion-related reactions.

You will receive corticosteroids before each infusion and you may also receive anti-histamines and/or medicines to reduce fever.

How much and how often you will be given Ocrevus

You will be given a total dose of 600 mg of Ocrevus every 6 months.

- The first 600 mg dose of Ocrevus will be given as 2 separate infusions (300 mg each), given 2 weeks apart. Each infusion will last about 2 hours 30 minutes.
- The following 600 mg doses of Ocrevus will be given as one single infusion. Each infusion will last about 3 hours 30 minutes or, if your you haven't had a bad reaction any infusion, your doctor may shorten your next infusion to 2 hours.

Your doctor will tell you how long your treatment with Ocrevus will last. If you have the impression that the effect of Ocrevus is too strong or too weak, tell your doctor or pharmacist

If you use more Ocrevus than you should

Since a healthcare professional will administer Ocrevus, he/she will control the dosage. However, in the event of overdoasge your doctor will manage the overdosage.

If you miss an infusion of Ocrevus

If you miss an infusion of Ocrevus, talk to your doctor to arrange to have it as soon as possible. Do not wait until your next planned infusion.

To get the full benefit of Ocrevus, it is important that you receive each infusion when it is due.

Effects when treatment with Ocrevus is stopped

- It is important to continue your treatment for as long as you and your doctor decides that it is helping you.
- After you stop Ocrevus treatment your blood B-cells will gradually increase to normal levels. This can take from six months to two and a half years, or up to several years in some cases.
- Before you start any other medicines, tell your doctor when you had your last Ocrevus infusion.

If you have any further questions on the use of Ocrevus, ask your doctor.

4. Possible side effects

Ocrevus can have side effects.

Not all side effects reported for Ocrevus are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Ocrevus, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor or nurse straight away if you think your MS is getting worse or if you notice any new symptoms. This may be due to a very rare and life-threatening brain infection called 'PML' which can cause symptoms similar to those of MS. PML has been seen with medicines similar to Ocrevus and other MS medicines.

The following side effects have been reported with Ocrevus:

Infusion-related reactions

Tell your doctor or nurse straight away if you experience any signs or symptoms of an infusion-related reaction during the infusion or up to 24 hours after the infusion.

- Infusion-related reactions are the most frequent side effect of Ocrevus treatment.

  Symptoms can 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
- flushing
- low blood pressure
- fever
- feeling tired
- headache
- feeling dizzy
- feeling sick (nausea)
- fast heart beat.

- If you experience an infusion-related reaction, you will be given medicines to treat it and the infusion may need to be slowed down or stopped. When the symptoms resolve, the infusion may be continued. If the infusion-related reaction is life-threatening, your doctor will permanently stop your treatment with Ocrevus.

Infections

- You might get infections more easily with Ocrevus**.**
- **Tell your doctor or nurse straight away if you notice any of these signs of infection during or after treatment:**
  - fever or chills

- cough which does not go away
- herpes (such as cold sore, shingles and genital sores).

- The following infections have been seen in patients treated with Ocrevus in MS.

  Very frequent:

  - upper respiratory tract infection
  - common cold or influenza.

  Frequent:

  - sinus infection
  - bronchitis (bronchial tube inflammation)
  - respiratory tract infection
  - viral infection
  - herpes infection (cold sore or shingles).

  Less frequent:

  - genital sores

Other frequent side effects

- problems sleeping
- cough
- build-up of thick mucus in the nose, throat or chest.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to

report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Report Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

5. How to store Ocrevus

- Store all medicines out of reach of children
- Store vial in a refrigerator at 2 ° - 8 °C.
- Keep vial in outer carton in order to protect from light.
- Do not freeze.
- Do not shake.
- Do not use this medicine after the expiry date (EXP) stated on the outer carton and on the vial label.
- Do not use the solution if the solution contains foreign particulate matter.

A sterile needle and syringe should be used to prepare the diluted infusion solution

Disposal of unused/expired medicine:

The release of pharmaceuticals in the environment should be minimised. Medicines should not be disposed of via wastewater and disposal through household waste should be avoided. Use established collection systems, if available in your location.

Contents of the pack and other information

What Ocrevus contains

Ocrevus contains 300 mg ocrelizumab per 10 mL.

Ocrevus contains the excipients polysorbate 20, sodium acetate dihydrate, αα-trehalose dihydrate and water for injection.

What Ocrevus looks like and contents of the pack

Ocrevus vials contain a clear to slightly opalescent and colourless to pale brown solution. Ocrevus is a 10 mL concentrate for solution for infusion supplied in either one or two, 15 mL single-use, colourless type 1 glass vials with a grey rubber stoppers laminated with fluororesin film and crimped with aluminium seals fitted with a green plastic flip-off caps.

The vials are packed into white cardboard boxes with black printing and a green marking over dosage form.

Not all packs may be marketed.

7. Holder of Certificate of Registration

Roche Products (Pty) Ltd

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Roche Ethical Assistance Line (REAL) toll-free: 0800 21 21 25

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