Package leaflet: Information for the patient

Ocrevus 920 mg solution for injection
ocrelizumab

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

What is in this leaflet

1. What Ocrevus is and what it is used for

What Ocrevus is

Ocrevus contains the active substance 'ocrelizumab'. It is a type of protein called a 'monoclonal antibody'. Antibodies work by attaching to specific targets in your body.

What Ocrevus is used for

Ocrevus is used to treat adults with:
- Relapsing forms of multiple sclerosis (RMS)
- Early primary progressive multiple sclerosis (PPMS)

What is Multiple Sclerosis

Multiple Sclerosis (MS) affects the central nervous system, especially the nerves in the brain and spinal cord. In MS, the immune system (the body's defence system) works incorrectly and attacks a protective layer (called myelin sheath) around nerve cells and causes inflammation. Breakdown of the myelin sheath stops the nerves working properly.

Symptoms of MS depend on which part of the central nervous system is affected and can include problems with walking and balance, weakness, numbness, double vision and blurring, poor coordination and bladder problems.

- **In relapsing forms of MS,** the patient has repeated attacks of symptoms (relapses). The symptoms can appear suddenly within a few hours, or slowly over several days. The symptoms disappear or improve between relapses but damage may build up and lead to permanent disability.

- **In primary progressive MS,** the symptoms generally continue to worsen from the start of the disease.

How does Ocrevus work?

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.

- **In Relapsing forms of MS (RMS)**, Ocrevus helps to significantly reduce the number of attacks (relapses) and significantly slow down the progression of the disease. Ocrevus also significantly increases the chance of a patient having no evidence of disease activity (brain lesions, relapses and worsening of disability).

- **In Primary Progressive MS (PPMS)**, Ocrevus helps to slow down the progression of the disease and reduce deterioration in walking speed.

2. What you need to know before you are given Ocrevus

You must not be given Ocrevus:

- if you are allergic to ocrelizumab or any of the other ingredients of this medicine (listed in section 6).
- if you currently have an infection.
- if you have been told that you have severe problems with your immune system.
- if you have cancer.

If you are not sure, talk to your doctor before you are given Ocrevus.

Warnings and precautions

Talk to your doctor before you are given Ocrevus if any of the following apply to you. Your doctor may decide to delay your treatment with Ocrevus, or may decide you cannot receive Ocrevus if:

- you have an **infection**. Your doctor will wait until the infection is resolved before giving you Ocrevus.
- you have ever had **hepatitis B** or are a carrier of the hepatitis B virus. This is because medicines like Ocrevus can cause the hepatitis B virus to become active again. Before your Ocrevus treatment, your doctor will check if you are at risk of 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.
- you have **cancer** or if you have had cancer in the past. Your doctor may decide to delay your treatment with Ocrevus.

Effect on the immune system:

- **Diseases that affect your immune system**: if you have another disease which affects the immune system. You may not be able to receive Ocrevus.
- **Medicines that affect your immune system**: if you have ever taken, are taking or are planning to take medicines that affect the immune system – such as chemotherapy, immunosuppressants or other medicines used to treat MS. Your doctor may decide to delay your treatment with Ocrevus or may ask you to stop such medicines before starting treatment with Ocrevus. See under ‘Other medicines and Ocrevus’, below for more information.

Injection reactions

- Injection reactions are the most common side effect of Ocrevus treatment given as an injection under your skin (subcutaneous injection).
- **Tell your doctor or nurse straight away if you have any injection reaction** (see section 4 for a list of injection reactions). Injection reactions can happen during the injection or up to 24 hours after the injection.
- To reduce the risk of injection reactions, your doctor will give you other medicines before each injection of Ocrevus (see section 3) and you will be observed during the injection and for at least one hour after the initial injection has been given.

Infections

- Talk to your doctor before you are given Ocrevus if you think you have an infection. Your doctor will wait until the infection is resolved before giving you Ocrevus.
- You might get infections more easily with Ocrevus. This is because the immune cells that Ocrevus targets also help to fight infection.
- Before you start treatment with Ocrevus and before subsequent injections, your doctor may ask you to have a blood test to verify your immune system because infections may occur more frequently in case of severe problems with your immune system.
- If you are treated with Ocrevus for primary progressive multiple sclerosis, and you have swallowing difficulties, Ocrevus may increase the risk of severe pneumonia.
- **Tell your doctor or nurse straight away if you have any of these signs of infection during or after Ocrevus treatment:**
  - fever or chills
  - cough that does not go away
  - herpes (such as cold sore, shingles or genital sores).
- **Tell your doctor or nurse straight away 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' (PML), which can cause symptoms similar to those of MS. PML can occur in patients taking Ocrevus.
  Tell your partner or carer about your Ocrevus treatment. They might notice symptoms of PML that you do not, such as memory lapses, trouble thinking, difficulty walking, sight loss, changes in the way you talk, which your doctor may need to investigate.

Vaccinations

- Tell your doctor if you have recently been given any vaccine or might be given a vaccine in the near future.
- While you are being treated with Ocrevus, you should not be given live or live attenuated vaccines (for example BCG for tuberculosis or vaccines against yellow fever).
- Your doctor may recommend that you are given a seasonal influenza vaccine.
- 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.

Children and adolescents

Ocrevus is not intended to be used in children and adolescents under 18 years old. This is because it has not yet been studied in this age group.

Other medicines and Ocrevus

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 that affect the immune system** – such as chemotherapy, immunosuppressants or other medicines used to treat MS. The effect on the immune system of these medicines with Ocrevus could be too strong. Your doctor may decide to delay your treatment with Ocrevus or may ask you to stop such medicines before starting treatment with Ocrevus.

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

Pregnancy

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. This is because Ocrevus may cross the placenta and affect your baby.
- Do not use Ocrevus if you are pregnant unless you have discussed this with your doctor. Your doctor will consider the benefit of you taking Ocrevus against the risk to your baby.
- Talk to your doctor before vaccinating your baby.

Contraception for women

Women who could become pregnant must use contraception:

- during treatment with Ocrevus and
- for 12 months after your last dose of Ocrevus.

Breast-feeding

Do not breast-feed while you are being treated with Ocrevus. This is because Ocrevus may pass into breast milk.

Driving and using machines

It is not known whether Ocrevus can affect your ability to drive or use tools or machines.
Your doctor will tell you whether your MS may affect your ability to drive or use tools and machines safely.

Ocrevus contains sodium

This medicine contains less than 1 mmol **sodium** (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Ocrevus is given

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 injection reactions (see sections 2 and 4 for information about injection reactions).
You will receive a corticosteroid and an anti-histamine before each injection and you may also receive medicines to reduce fever.

How much and how often you will be given Ocrevus

You will be given a total dose of 920 mg of Ocrevus every 6 months.

How Ocrevus is given

- Ocrevus will be given to you by a doctor or a nurse. It will be given as an injection under your skin (subcutaneous injection).
- Injections will be given in the stomach in approximately 10 minutes.
- Your doctor or nurse will make sure each injection is given in the stomach, where the skin is not red, bruised, tender, hard, or areas where there are moles or scars.
- You will be observed while you are being given Ocrevus and for at least 1 hour after the initial injection has been given. This is in case you have any side effects such as injection reactions. The injection may be temporarily stopped or permanently stopped if you have an injection reaction, depending on how serious it is (see sections 2 and 4 for information about injection reactions).

If you miss an injection of Ocrevus

- If you miss an injection of Ocrevus, talk to your doctor to arrange to have it as soon as possible. Do not wait until your next planned injection.
- To get the full benefit of Ocrevus, it is important that you receive each injection when it is due.

If you stop Ocrevus treatment

- It is important to continue your treatment for as long as you and your doctor decide that it is helping you.
- Some side effects can be related to having low B cells. After you stop Ocrevus treatment, you may still experience side effects until your B-cells return to normal. 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 rare cases.
- Before you start any other medicines, tell your doctor when you had your last Ocrevus dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with Ocrevus:

<u>Serious side effects:</u>

Injection reactions

- Injection reactions are the most common side effect of Ocrevus treatment given as a subcutaneous injection (very common: may affect more than 1 in 10 people). In most cases these are mild or moderate reactions but serious reactions have happened with Ocrevus treatment given as an infusion in a vein (intravenous infusion).
- **Tell your doctor or nurse straight away if you experience any signs or symptoms of an injection reaction during the injection or up to 24 hours after the injection.** 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 have an injection reaction, you may be given medicines to treat it and the injection may need to be stopped. If the injection reaction is life-threatening, your doctor will permanently stop your treatment with Ocrevus.

Infections

- You might get infections more easily with Ocrevus. The following infections have been seen in patients treated with Ocrevus in MS:
  - **Very common** (may affect more than 1 in 10 people)
    - sore throat and runny nose (upper respiratory tract infection)
    - flu
  - **Common** (may affect up to 1 in 10 people)
    - sinus infection
    - bronchitis (bronchial tube inflammation)
    - herpes infection (cold sore or shingles)
    - infection of the stomach and bowel (gastroenteritis)
    - respiratory tract infection
    - viral infection
    - skin infection (cellulitis)

  Some of them might be serious.

- **Tell your doctor or nurse straight away if you notice any of these signs of infection:**

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

<u>Other side effects:</u>

Very common (may affect more than 1 in 10 people)
- decrease in specific proteins in the blood (immunoglobulins) which help protect against infection

Common (may affect up to 1 in 10 people)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- cough
- a build-up of thick mucus in the nose, throat or chest
- low levels of a type of white blood cell (neutropenia)

Not known (it is not known how often these side effects happen)
- a reduction in white blood cells which can be delayed

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ocrevus

Ocrevus will be stored by the healthcare professionals at the hospital or clinic under the following conditions:

- This medicine is to be kept out of the sight and reach of children.
- This medicine is not to be used after the expiry date which is stated on the outer carton and the vial label after 'EXP'. The expiry date refers to the last day of that month.
- This medicine is to be stored in a refrigerator (2^{o}C - 8^{o}C). It is not to be frozen. The vials are to be kept in the outer carton to protect them from light. Do not shake.

Do not throw away any medicines via wastewater. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ocrevus contains

- The active substance is ocrelizumab. Each vial contains 920 mg of ocrelizumab in 23 mL at a concentration of 40 mg/mL.
- The other ingredients are recombinant human hyaluronidase (rHuPH20), sodium acetate trihydrate (see Section 2 'Ocrevus contains sodium'), glacial acetic acid, α,α-trehalose dihydrate, polysorbate 20, L-methionine and water for injections.

What Ocrevus looks like and contents of the pack

- Ocrevus is a clear to slightly opalescent, and colourless to pale brown solution.
- It is supplied as a solution for injection.
- Ocrevus is available in a pack containing 1 glass vial.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Read the SmPC for additional information.

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

To prevent medication errors, it is important to check the vial labels to ensure that the correct formulation (intravenous or subcutaneous formulation) is being given to the patient by the correct route, as prescribed.

The medicinal product should be inspected visually to ensure there is no particulate matter or discolouration prior to administration.

The medicinal product is for single use only and should be prepared by a healthcare professional using aseptic technique.

Ocrevus SC is a ready-to-use solution for subcutaneous injection only and should not be diluted or mixed with other medicinal products.

No incompatibilities between this medicinal product and polypropylene (PP), polycarbonate (PC), polyethylene (PE), polyvinyl chloride (PVC), and polyurethane (PUR) and stainless steel have been observed.

Preparation of the syringe

The medicinal product does not contain any antimicrobial preservative. If the dose is not administered immediately, refer to "Storage of the syringe" below.

- Prior to use, remove the vial from the refrigerated storage and allow the solution to come to room temperature.
- Withdraw the entire contents of Ocrevus SC solution from the vial with a syringe and transfer needle (21G recommended).
- Remove the transfer needle and attach a SC infusion set (e.g., winged/butterfly) containing a 24-26G needle for injection. Use a SC infusion set with residual hold-up volume NOT exceeding 0.8 mL for administration. DO NOT administer any residual hold-up volume remaining in the SC infusion set to the patient.
- Prime the SC infusion line with the drug product solution to eliminate the air in the infusion line and stop before the fluid reaches the needle.
- Ensure the syringe contains exactly 23 mL of drug product solution after priming and expelling any excess volume from the syringe.
- Administer immediately to avoid needle clogging. DO NOT store the prepared syringe that has been attached to the already-primed SC infusion set.

Storage of the syringe

- If the dose is not to be administered immediately, use aseptic technique to withdraw the entire contents of Ocrevus SC solution for injection from the vial into the syringe to account for the dose volume (23 mL) and priming volume for the SC infusion set. Replace the transfer needle with a syringe closing cap. DO NOT attach an SC infusion set for storage.
- From a microbiological point of view, the product should be used immediately once transferred from the vial to the syringe since the medicine does not contain any antimicrobial-preservative. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and normally not longer than 24 hours at 2 °C to 8 °C.
- If preparation has taken place under controlled and validated aseptic conditions, the closed syringe can be stored for up to 30 days in the refrigerator at 2 °C to 8 °C followed by 8 hours in diffuse daylight at temperatures ≤30 °C.

- If the syringe was stored in a refrigerator, allow the syringe to reach room temperature prior to administration.

Method of Administration

The 920 mg dose (23 mL) should be administered as a subcutaneous injection in the abdomen in approximately 10 minutes. Use of a SC infusion set (e.g., winged/butterfly) is recommended.

The injection site should be the abdomen, except for 2 inches (5 cm) around the navel. Injections should never be given into areas where the skin is red, bruised, tender, or hard, or areas where there are moles or scars.

Ocrevus SC should always be administered by a healthcare professional. For the initial dose, post-injection monitoring with access to appropriate medical support to manage severe reactions such as injection reactions, for at least one hour after injection is recommended. For subsequent doses, the need for post-injection monitoring is at the treating physician's discretion (see section 4.4 of the SmPC).