

- **What is Ocrevus?**

Ocrevus is a disease modifying therapy which is available for both relapsing forms of MS and early primary progressive MS.

- **How does Ocrevus work?**

Ocrevus is a humanised monoclonal antibody which targets CD-20 positive B cells, a specific type of immune cell which is believed to be a key contributor to myelin damage in MS. Ocrevus works by binding to CD20 cell surface proteins which are expressed on certain B cells and destroying them.

- **Who should take Ocrevus?**

Ocrevus can be prescribed for adults with relapsing and early primary progressive forms of MS. It must be prescribed by a neurologist.

### **Contraindications**

It is important that you tell your healthcare team if you have any health problems or are taking other medicines.

Ocrevus may not be appropriate if you have existing medical conditions including cancer or serious infections such as HIV/AIDS or hepatitis B.

### **Conception and pregnancy**

Pregnancy is not recommended during treatment with Ocrevus. If you plan to start a family, you should discuss your specific circumstances with your healthcare team.

Women of child-bearing age must use an effective method of contraception during treatment and for 12 months after stopping Ocrevus.

- **How is Ocrevus administered?**

Ocrevus is administered via an intravenous infusion (drip) in hospital. The first dose of Ocrevus is given as two separate infusions, two weeks apart. Further doses are given as one infusion every six months. The infusions normally take about 2 to 4 hours to complete. Pre-mediation is given 30-60 minutes prior to the infusion of Ocrevus – these help to minimise reactions during the infusion.

You may be asked to stay for one hour after an infusion for observation.

- **What are the side-effects from taking Ocrevus?**

Common [side effects](#) include:

- infusion related reactions such as headache, rashes, fever and nausea.

Many people treated with Ocrevus experience these reactions, but they are normally mild to moderate and are short-lived. To minimise infusion reactions, you may be given additional medications before infusions, and be monitored closely during the infusion.

- infections including coughs, colds, chest infections and herpes virus infections (such as cold sores or shingles)

Ocrevus suppresses part of the immune system so that you will be more vulnerable to infections such as colds and viruses. Your healthcare team should give advice on ways to minimise the risk of infections.

Common side effects (affecting more than 1 person in 100)

- infusion-related reactions
- flu (influenza)
- sinus infections
- bronchitis (bronchial tube inflammation)
- herpes infection (cold sore or shingles)
- infection of the stomach and bowel (gastroenteritis)
- viral infections
- skin infection (cellulitis)

A full list of side effects is included in the manufacturer's patient information sheet which is available here: <https://www.medicines.ie/medicines/ocrevus-300-mg-concentrate-for-solution-for-infusion-33182/patient-info?page=1&per-page=25>

### **Assessment before treatment**

Before starting Ocrevus, you will have tests to check for HIV and hepatitis B. Your white blood cell levels will also be checked. If you take medicine for high blood pressure, you may be asked to stop taking it for 12 hours before each infusion, as Ocrevus can lower blood pressure.

### **Assessment during treatment**

Before each infusion you will be given a corticosteroid and an anti-histamine and you may also be given medicine to reduce fever. This is to reduce any infusion reaction. You will be closely monitored for reactions such as a rash or itchy skin, fever, nausea or headache. The infusion may be slowed, temporarily stopped or permanently stopped if you have an infusion reaction, depending on how serious it is.

## **What are the findings from the Ocrevus clinical trials?**

### **Ocrevus research for relapsing remitting MS**

- **Opera I and II - Ocrevus compared to interferon beta 1a (Rebif)**

These phase III studies recruited 1656 participants with relapsing remitting MS who took either Ocrevus 600mg every 6 months or interferon beta 1a (Rebif) three times per week for approximately two years.

Over the two years of the clinical trials, Ocrevus reduced the number of relapses by 46% compared to interferon beta 1a, reduced disability progression sustained for 3 and 6 months, and significantly reduced the number of lesions seen on MRI scans compared to beta interferon. Brain volume loss was reduced and numbers of participants with no evidence of disease progression (NEDA) were increased in the Ocrevus treatment groups compared to interferon beta 1a.

### **Research on Ocrevus for progressive MS:**

- **ORATORIO - Ocrevus compared to placebo**

This phase III study recruited 732 participants with primary progressive MS and EDSS of 3 to 6.5 who took either Ocrevus or placebo by iv infusion every 6 months for more than 2 years.

The main measure of the study was the onset of disability progression. This was measured by the number of participants with an increased EDSS which was still evident 3 months later. The study also recorded the number of participants with an increased EDSS still evident after 6 months, walking speed over 25 feet and volume of brain and MS lesions.

Fewer people taking Ocrevus had an increase in disability, compared to placebo. An increase in disability which lasted 3 months was seen in 30.2% of those taking Ocrevus and 34% of those taking placebo. In addition, increased disability which lasted at least 6 months was seen in 28.3% taking Ocrevus and 32.7% taking placebo. Comparing the two groups, people taking Ocrevus were 24% less likely to have an increase in their disability than those taking placebo.

After 120 weeks of treatment, walking speed change over 25 feet was 39% slower for Ocrevus compared to 55% slower for placebo. Brain lesion volume decreased by 3.4% with Ocrevus and increased by 7.4% with placebo. Loss of brain volume was 0.9% for Ocrevus and 1.09% for placebo.

**Is Ocrevus covered on a reimbursement scheme?**

Ocrevus is currently reimbursed for those with relapsing and early primary progressive forms of MS