

PATIENT BROCHURE

Ocrevus in the treatment of relapsing forms of multiple sclerosis

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

This brochure gives you information about what Ocrevus is, how it works and what you can expect from your treatment.

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Indication and dosage

Ocrevus (ocrelizumab) is used to treat adults with relapsing forms of multiple sclerosis (RMS).

Ocrevus is given as intravenous infusions twice a year at the hospital. It is recommended to have laboratory tests taken before its administration.

Your doctor will ascertain that Ocrevus treatment is suitable for you. The more you know about your disease and treatment, the better your treatment team and your closest ones can help you live the way you want.



Information about multiple sclerosis

Multiple sclerosis (MS) is a progressive neurological disease that affects the central nervous system, i.e. your brain and spinal cord. Myelin (myelin sheath) is a substance that covers nerve fibres (axons) and improves transmission of electric impulses in the axons.

In multiple sclerosis, body's own defence system mistakenly attacks against myelin covering the axons and thus damages them. This slows down or prevents transmission of signals from the central nervous system to other parts of the body.

White blood cells are part of the natural defence system and their function is to search, identify and destroy foreign substances in the body.

In multiple sclerosis, T cells and B cells (types of white blood cells) are transported from the circulation to the central nervous system where they cause an inflammatory reaction and myelin damage. Reason for this is currently not known.

Damage is caused when white blood cells mistakenly identify myelin as a foreign structure and thus attack against it.



Did you know?

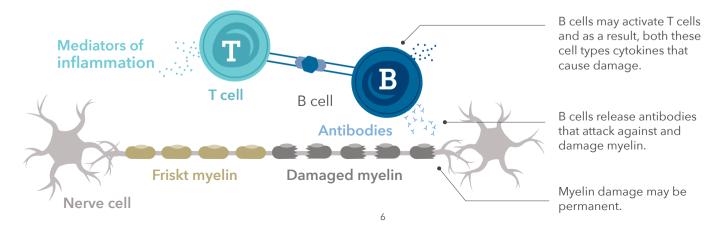
- Relapsing forms of MS in women are twice as common as in men
- Onset most commonly at the age of 20-40 years
- More than 12,000 people suffer from multiple sclerosis in Finland
- Multiple sclerosis is diagnosed by a specialist in neurology, i.e. a neurologist

How does a myelin damage develop?

In multiple sclerosis, white blood cells in the body, i.e. B cells and T cells, are transported to the central nervous system, i.e. to the brain and spinal cord area. For a reason currently not known, this causes a local inflammation

This inflammation is caused, for example, by the effects of cytokines and antibodies released by B cells and T cells. This leads to damage in myelin that is an important supportive agent in neuronal signalling.

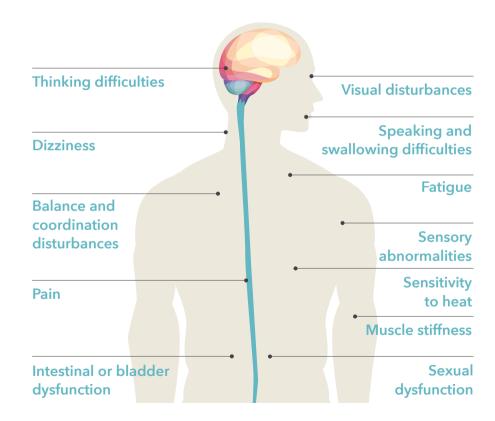
The inflammatory reaction may also lead to formation of scar tissue that disrupts interneuronal signalling. Nerve damage and disrupted signalling in the central nervous system can be seen as symptoms and imaging findings of multiple sclerosis.



Symptoms of multiple sclerosis vary

Multiple sclerosis and its symptoms may vary substantially between persons and affect different areas.

Symptoms differ depending on which parts of the central nervous system are affected and of the amount of nerve damage.



Relapsing forms of Multiple Sclerosis (RMS)

Asymptomatic periods, i.e. remissions

Patients with relapsing forms of MS may have long asymptomatic periods with exacerbation of the disease, i.e. relapses, between these periods.

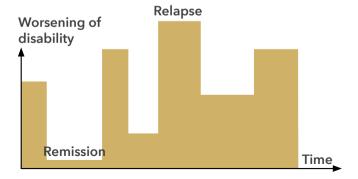
Did you know?

- Exacerbation of the disease,
 i.e. a relapse, may show as new
 neurological symptoms or sudden
 and clear worsening of previous
 symptoms of MS for at least 24 h.
- Relapses can be treated. If you suspect a relapse, contact your treatment unit.

Exacerbations of the disease, i.e. relapses

Relapses recur periodically and vary in duration. During a relapse, symptoms can develop suddenly within a few hours or slowly over several days.

Once MS progresses, damage caused by relapses may be permanent and worsen disability.

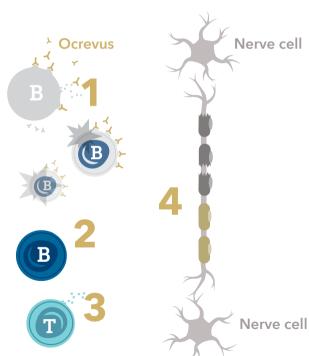


Mechanism of action of Ocrevus

Ocrevus targets to B cells. This reduces inflammation, number of relapses and slows down progression of the disease.

- 1. Ocrevus only destroys certain types of B cells. This inhibits the release of antibodies and cytokines secreted by these cells.
- 2. Ocrevus does not bind to all B cells in the body, but it only destroys the type of B cells that may play a role in MS.
- 3. Destruction of B cells also affects the activation of T cells.
- 4. Inflammation and myelin damage reduce.

Ocrevus increases significantly the chance of a patient having no evidence of disease activity (brain lesions, relapses and worsening of disability).



What should you consider before treatment with Ocrevus can be initiated?

Talk to your doctor before your treatment is initiated

- If you have an infection, since it is only possible to give Ocrevus after the infection has resolved.
- If you have ever had hepatitis B or if you are a carrier of the hepatitis B virus. Your doctor will check if you are at risk of hepatitis B infection.

- If you have cancer or if you have had cancer in the past.
 Treatment with Ocrevus may be delayed to a later time point.
- If you have another disease which affects your immune system, you may not be able to receive Ocrevus.
- 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.

Effects from these medicines and Ocrevus on the immune system may 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 you are taking medicines for high blood pressure, since lowering of blood pressure may occur during the infusion with Ocrevus. It is therefore recommended to transiently discontinue your treatment with medicines for high blood pressure on the day when the infusion is given.
- If you have recently been given any vaccination or you are planned to receive a vaccination in the near future. Possible vaccinations should be given 6 weeks before initiation of the treatment with Ocrevus.

- If you are pregnant, think that you may be pregnant or are planning to have a baby.
 Women must use contraception during treatment with Ocrevus and for 12 months after their last infusion of Ocrevus.
- Tell your doctor if you use any natural products.

Blood tests will be taken from you before Ocrevus infusion is given.

Your doctor will decide whether treatment with Ocrevus can be given to you or whether administration of the treatment should be delayed.

Remember to always give your doctor all the information about your health status.

Ocrevus is administered as intravenous infusions twice a year



Starting dose will be given as two separate infusions of 300 mg.

The next infusions will be given as 600 mg single infusions 6 months apart.

For optimal treatment results, it is important that Ocrevus treatment is given when it is due. If you cannot arrive for a scheduled treatment, contact your treatment team and make a new appointment.

What happens on your infusion day?

Reserve 5 hours for the administration of the first two doses of Ocrevus and 4-6 hours for each subsequent Ocrevus infusion. Administration of the infusion itself takes 2-3,5 hours depending which infusion option is used (administration of the starting dose takes 2.5 hours). The entire treatment process also includes preparation and a minimum of one hour of monitoring after administration of the infusion.

If you are on blood pressure lowering medication, it is recommended to transiently discontinue this medication on the day when the infusion is given.

RFFORF INFUSION INFLISION **INFUSION AFTER** THE INFUSION **DAY 1 + DAY 15** 6 MONTHS APART 6 MONTHS APART THE INFUSION **OPTION 1 OPTION 2*** The infusion will The infusion will The infusion will 1 hour after the 30-60 min before the infusion last 2.5 hours last 3.5 hours last 2 hours infusion You will be given Administration of Your condition Administration Administration the premedication the first two 300 of each 600 mg of each 600 mg will be monitored prescribed by your infusion lasts infusion lasts closely for 1 hour mg infusions lasts

2.5 hours

doctor

3.5 hours

2 hours

after the infusion

^{*}If patient did not experience a serious infusion-related reaction (IRR) with any previous Ocrevus infusion.

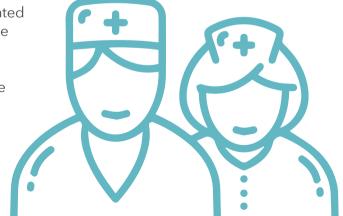
Information about infusion-related reactions

Any medicinal treatment can cause side effects, although not everybody gets them.

The most common side effect from the treatment with Ocrevus is infusion-related reactions. However, these can be treated. You will receive premedication before each infusion to reduce frequency and severity of infusion-related reactions.

Health care personnel at your clinic has been trained in case of infusion-related reactions. If you experience infusion-related reactions, your treatment team may, for example, reduce the infusion rate or discontinue your infusion.

Your condition will be monitored for at least 1 hour after the infusion. Infusion-related reactions may occur during the infusion or up to 24 hours after the infusion. Reactions are more likely during the first infusion.



On the day after the infusion and between the infusions

Side effects from Ocrevus treatment may include

- infusion-related reactions
- upper respiratory infections
- decrease in specific proteins in the blood (immunoglobulins).

Contact your treatment team immediately, if you experience any symptoms of an infection, such as

- fever and/or chills
- persistent cough
- Herpes: unusual cold sores, symptoms associated with genital herpes, e.g. sores, shingles



Blood tests will be taken from you before Ocrevus infusion is given. No other laboratory tests are required regularly during the treatment with Ocrevus. However, your doctor may have these taken at his/her discretion. If you are not feeling well or your MS worsens, contact immediately your treatment team, doctor or nurse.

Other important information about your treatment

Vaccinations

Vaccinations should be given at least 6 weeks before initiation of the treatment with Ocrevus.

You should not be given live or live attenuated vaccines.

or live attenuated vaccines during this treatment.

Taking a seasonal influenza vaccine may be recommended to you.

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Pregnancy

Women of childbearing potential must use contraception during treatment with Ocrevus and for 12 months after their last infusion of Ocrevus.

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Breast-feeding

It is recommended to stop breast-feeding during the treatment with Ocrevus.

Healthy lifestyle supports your medicinal treatment and helps in maintaining your functional ability

Follow a balanced and healthy diet

A healthy diet includes plenty of fibre-rich vegetable and wholegrain products, moderately fish, meat and milk products as well as an appropriate amount of dietary fats, preferably vegetable fats. Remember to favour Finnish seasonal products, such as berries, mushrooms, vegetables and root vegetables.



Vitamin D

Vitamin D has been shown to have effects protecting from multiple sclerosis. Vitamin D supplement is necessary particularly if you mainly stay indoors and your diet does not contain fish or other sources of vitamin D. It is recommended for patients with MS to take vitamin D supplement during the dark season in the winter or all year round, if necessary.

Exercise, exercise

An appropriate amount of the type of exercise comfortable to you helps maintain your functional ability and increase your energy levels.



Exercising regularly also elevates your mood. Nice, gentle forms of exercise include

- Walking
- Stretching
- Yoga
- Swimming and pool workout

Functional exercising, such as household chores, shopping, gardening and hiking in the nature, is also a good form of exercise.

Sleep and rest

People must rest to be able to lead an active life. Rest is necessary to counterbalance physical strain and it is also good to recover from mental strain by resting and relaxing. Sleep provides total rest and recovery. While sleeping, we



"charge our batteries" and our body rests both physically and mentally. Our brain rests during sleep.

You can try to control your stress levels by using different relaxation techniques and by trying to maintain a positive mood.

Give up smoking

Smoking is a significant risk factor for MS. Nonsmoking and giving up smoking are part of the treatment of MS.



Notes

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