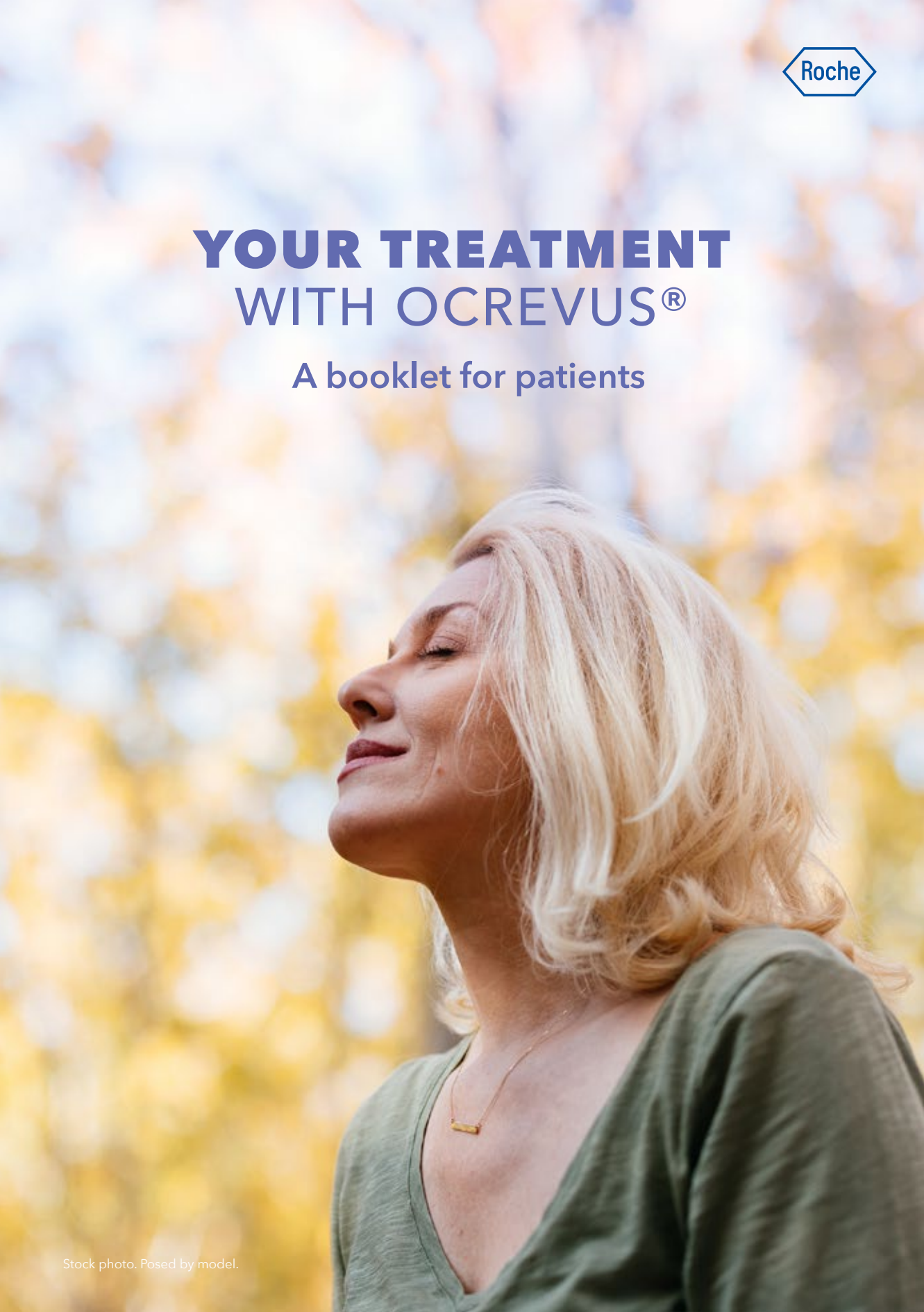
YOUR TREATMENT WITH OCREVUS®

A booklet for patients



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YOUR THERAPY COMPANION FOR OCREVUS®

For treatment of:

- active relapsing forms of multiple sclerosis (MS);
- primary progressive multiple sclerosis (PPMS).

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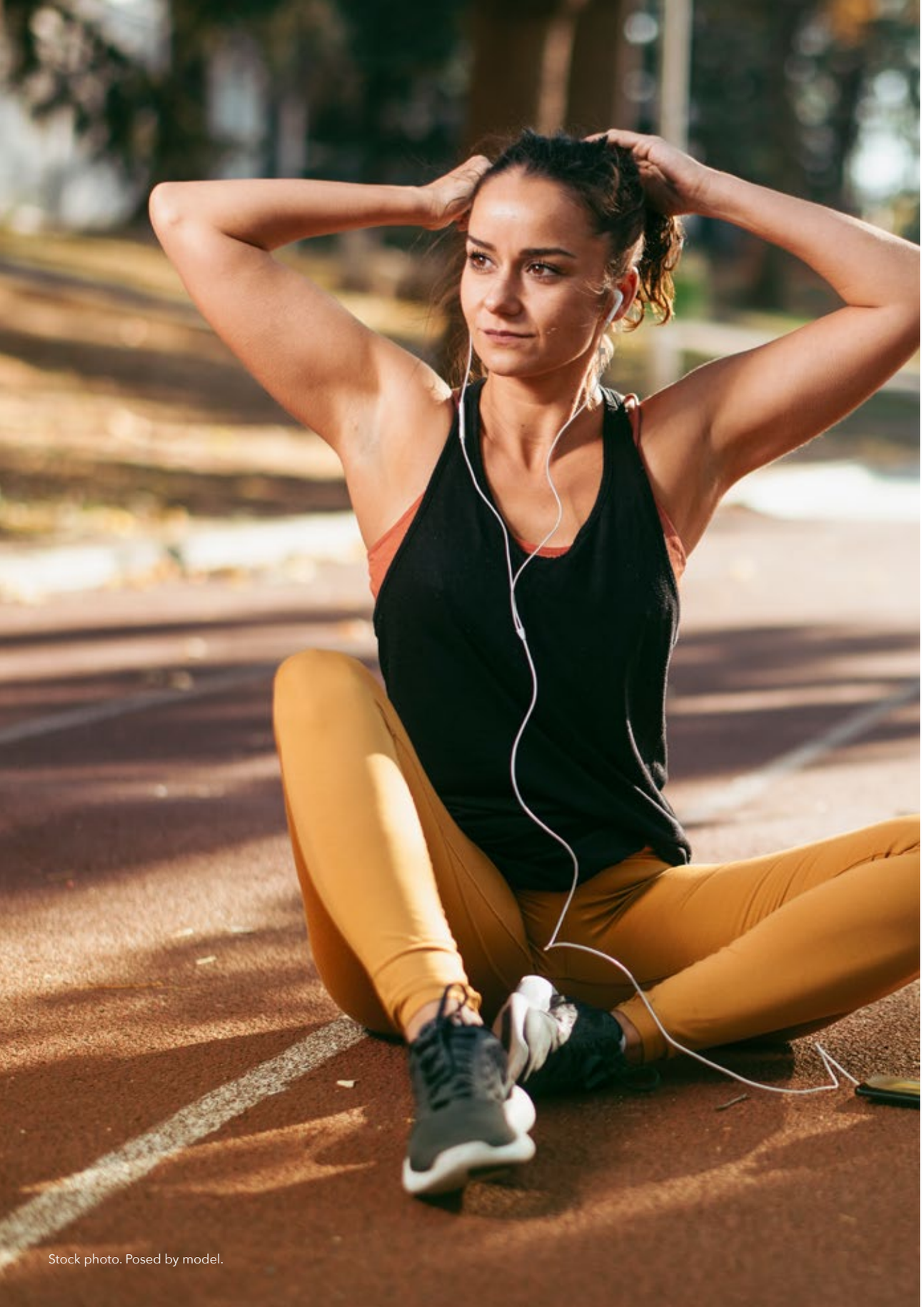

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DEAR PATIENT,

This treatment companion provides you with important safety information to help you understand the benefits and risks associated with OCREVUS®. Use this guide to learn more about your condition and what you can expect from your treatment with OCREVUS®. This guide is also intended for all those who are close to and support people with MS or PPMS. If you have any further questions, you should contact your doctor.*

Scan the QR code to get further information for patients and relatives on the Focus on Humans platform.
www.roche-fokus-mensch.ch

*The generic masculine chosen in this brochure refers simultaneously to male, female and other gender identities.

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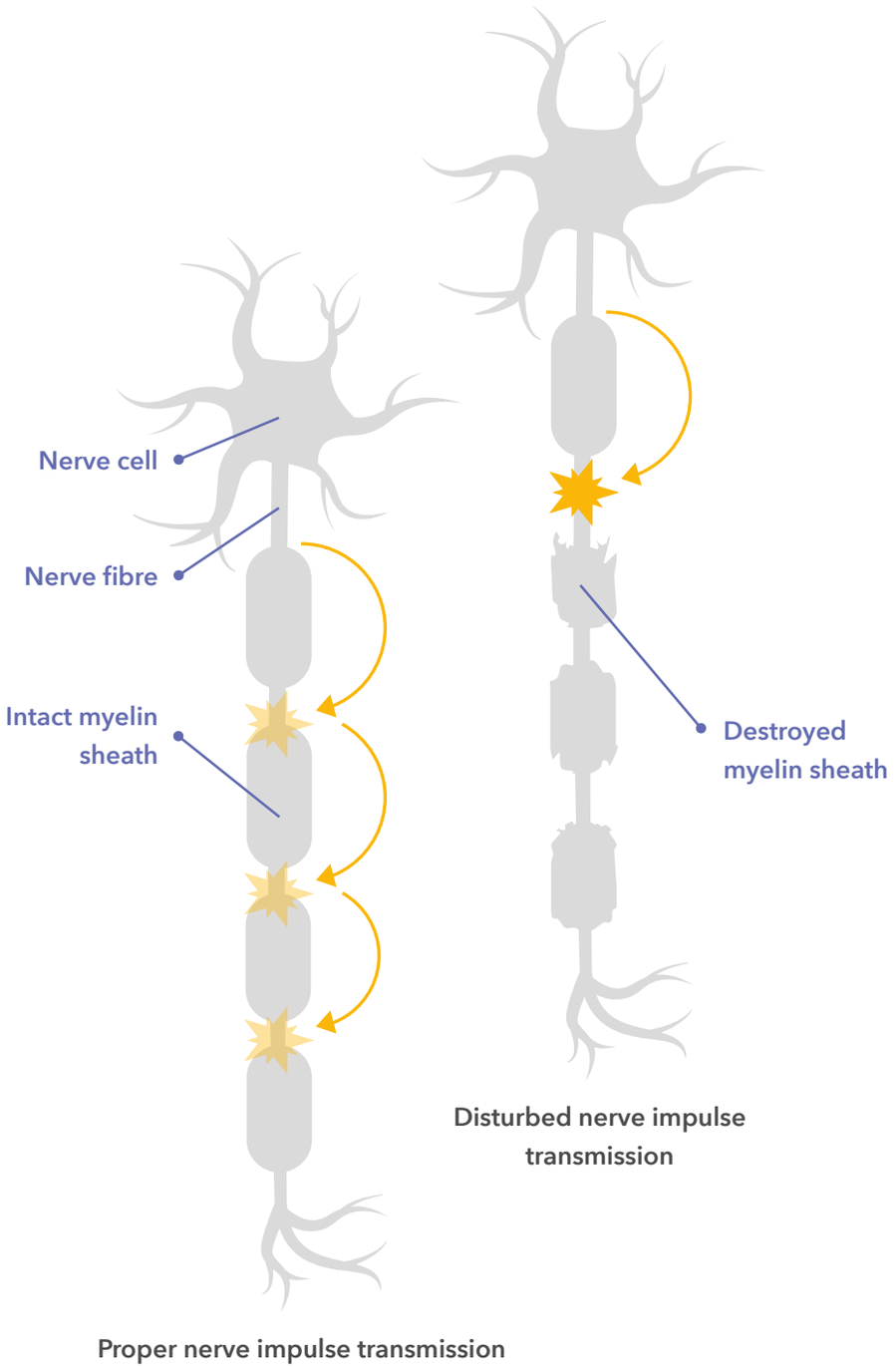
01 MS: A DISEASE OF A THOUSAND FACES

Multiple sclerosis is a chronic inflammatory disease of the central nervous system (CNS) and belongs to the so-called autoimmune diseases. These mean that the defense system is not only directed against pathogens such as viruses and bacteria. Rather, it attacks the body's own structures. In the case of MS, these are the sheaths of the nerve fibres in the brain and spinal cord called myelin sheaths.

Myelin sheaths support impulse transmission between the CNS and the muscles and thus ensure coordinated movements. If themyelin sheath is damaged by permanent inflammation, the information now only arrives at the destination incompletely or even does not arrive at all. However, since these inflammations can occur at very different points in the brain and spinal cord, MS is characterised by a wide range of symptoms: for example, the sensitivity on the arms or legs may be disturbed. Also, if the optic nerve is inflamed, you can see things like through a dense fog – double or blurred vision. Other symptoms may be movement disorders. Many patients also suffer from severe tiredness (fatigue) or poor concentration. MS manifests quite individually and is therefore often called the disease of a thousand faces.



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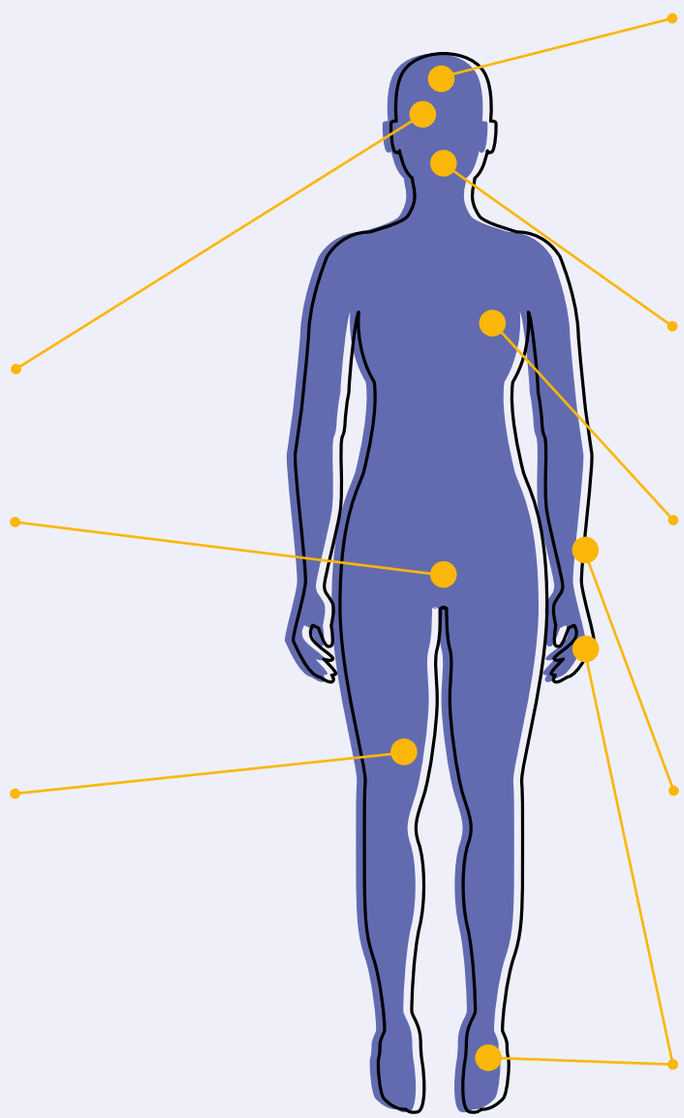
Identify possible signs

Talk to your doctor about the possible symptoms that may occur in the course of MS. These may vary greatly over the course of the disease. It is very helpful if you keep a symptom diary and bring it with you to the follow-up appointments to discuss it with the treating doctor.



Cognitive impairment
Reduction of mental capacity, limited attention, memory and concentration, balance and coordination problems

Vision disorders
Blurred or foggy vision, double images

Speech disorders
Slurred speech, swallowing disorder

Bladder disorders
Bladder emptying disorder, urinary urgency (imperative urination) not easily controlled, incontinence

Fatigue
Premature exhaustion, lack of motivation, disturbed sleep pattern, frustration or irritability

Muscle weakness
Spasticity, paralysis, feeling stiff, tremor

Sensory disorders
Sensory disturbances of the skin, usually in the form of tingling, (painful) abnormal sensations or numbness

Mobility restrictions
Unsteadiness during walking or grabbing

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Thousand faces – various forms of disease

Even if MS manifests differently in each affected person, three typical forms can be distinguished: relapsing remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS).

01 *Relapsing remitting MS (RRMS)*

From relapse to relapse
In most MS patients, the disease initially proceeds in relapses. This form of disease affects women more frequently than men. Patients are generally diagnosed with this between the age of 20 and 40. In RRMS, symptoms either completely or partially regress after a relapse. Later, the MS often proceeds in an increasingly continuous progression. This type of progression is then called SPMS. As long as there are further relapses in the transition phase between RRMS and SPMS, this is referred to as SPMS with intermittent relapses (relapsing SPMS, or rSPMS). Both forms, RRMS and rSPMS, fall into the category of RMS (relapsing multiple sclerosis).

02 *Secondary progressive MS (SPMS)*

A second stage
As already mentioned, this form of disease is often the second stage of the disease, as it develops from the relapsing MS in around half of the patients and only occurs in the early phase. The characteristic of the SPMS is a continuous course without relapses, but invisibly continuous increase in restrictions for the patient.

03 *Primary progressive MS (PPMS)*

Continuous progression
This form of MS often occurs only after the age of 40 and is the rarest form of the disease. The onset of the disease is continuous and gradual. Relapses are very rare, as the disease progresses inconspicuously. Once damage has occurred, it is no longer possible to repair it and physical restrictions come about more quickly.

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Progression

A fundamental term for understanding MS is progression. This means the advancement or worsening of a disease. But how does disease progression occur in MS? Due to the inflammatory processes typical of MS, damage to the nerves and therefore the adverse effects intensify. This can happen as part of a relapse, for instance. In some cases, the symptoms no longer fully regress and worsen permanently. The medical term is relapse-associated worsening, or **RAW**. This means that the MS deteriorates by leaps and bounds, in relapses.

Today, however, it is known that MS can continue to be active even if no relapses occur and thus silently cause permanent damage to the nerves. This gradual progression is referred to as the progression independent of relapse activity (**PIRA** for short).

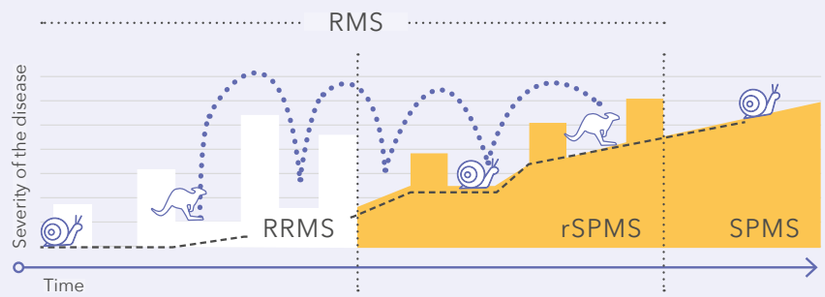
RAW

As a mnemonic, you can remember this relapse-dependent progression of the MS with the image of the kangaroo.

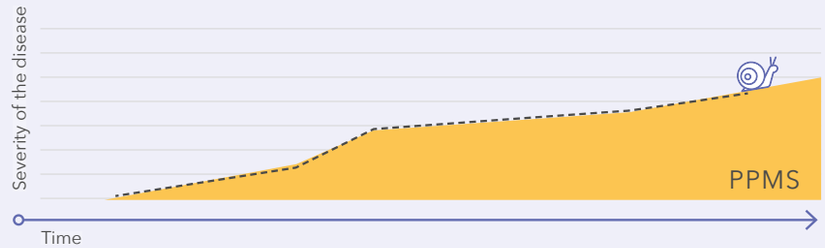
PIRA

Imagine a snail that slowly but steadily goes its way. In the same way, MS may progress surreptitiously, but permanently.

Course of disease in RRMS and SPMS



Course of disease in PPMS



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02 LOTS OF PUZZLE PIECES, ONE DIAGNOSIS

MS is manifested with many faces, and its initial symptoms may also indicate other diseases. Therefore, it usually takes many investigations to confirm the diagnosis.

The first step towards diagnosis is a detailed discussion with the neurologist. In this way, they can determine your previous medical history and get an overall overview, for example of medications taken, possible allergies and familial diseases.

This so-called medical history collection is followed by a physical examination. This is when the doctor tests the sensitivity of the skin and its reaction to heat, cold and vibration. He also checks the reflexes and mobility of various muscles in the arms, legs and face. The sense of balance and coordination are also tested.

Other signs of the MS are inflammation foci, so-called lesions, in the brain or spinal cord. These can be detected by certain tests, as can certain proteins in the cerebrospinal fluid. These can also be a sign of MS.

You will find information on the possible individual investigations in the following overview.

Overview of investigations

Blood test:
Even if there is no test that can detect MS via the blood, the blood test can exclude other possible diseases.

Magnetic resonance imaging (MRI):
This procedure allows the doctor to make images of the brain and sometimes of the spinal cord. The typical inflammatory foci can be recognized at this early stage in 85 percent of patients. MRI can support the diagnosis of MS and help to control the course of the disease.

Investigation of the cerebrospinal fluid (CSF diagnostics):
The cerebrospinal fluid (CSF) flows around the nerve cells in the central nervous system and protects the brain and spinal cord from external influences. About two thirds of MS patients are found to have an increased amount of certain proteins, known as oligoclonal bands, in the cerebrospinal fluid. In this way, this finding can support the diagnosis of MS. To obtain cerebrospinal fluid, the doctor performs lumbar puncture.

Investigation of nerve function:
Since the myelin sheaths are destroyed in MS, impulses are transmitted more slowly. With the help of the so-called evoked potentials, the doctor can determine the conductivity and functionality of the nerve pathways.

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03 COMPLEX SYSTEM, TARGETED EFFECT

Your doctor has prescribed OCREVUS® to you. OCREVUS® is approved for the treatment of patients with active relapsing forms of MS or primary progressive MS (PPMS). The active substance ocrelizumab is a special antibody that can make certain misdirected cells in the immune system harmless in the case of MS and thereby reduce inflammation processes in the myelin layer.

Our **immune system** is a highly complex combination of various organs, cells and molecules. Its purpose is to protect the body from harmful intruders. In some people, the immune system suddenly turns against the body's own structures and attacks them. This is how an autoimmune disease such as MS can arise. It has not yet been established for sure why the immune system gets misdirected.

What is the role of misdirected B cells?

In MS, defense cells wrongly attack the protective covering (myelin layer) of nerve fibres in the brain and spinal cord. T cells and B cells, which belong to white blood cells, play an important role here. It has already been known for some time that T cells play a role in MS. But B cells are also of great importance in MS. Misdirected B cells release inflammatory substances (cytokines) and produce antibodies that bind to myelin and attract other defense cells. In MS, misdirected B cells contribute to the damage of myelin in many ways. In addition, they give signals to T cells, so that they also drive the inflammation process.

Targeted therapy reduces inflammation

OCREVUS® offers targeted B-cell therapy. The active substance ocrelizumab is a therapeutic antibody that binds only to specific B cells, those that carry the protein CD20 on their surface. These cells are in an activated state, causing inflammation and thereby damaging the myelin layer. OCREVUS® attacks only CD20-positive B cells and renders them harmless, which leads to a reduction in inflammatory processes. Other B-cell types and the other cells of the immune system remain largely unaffected.

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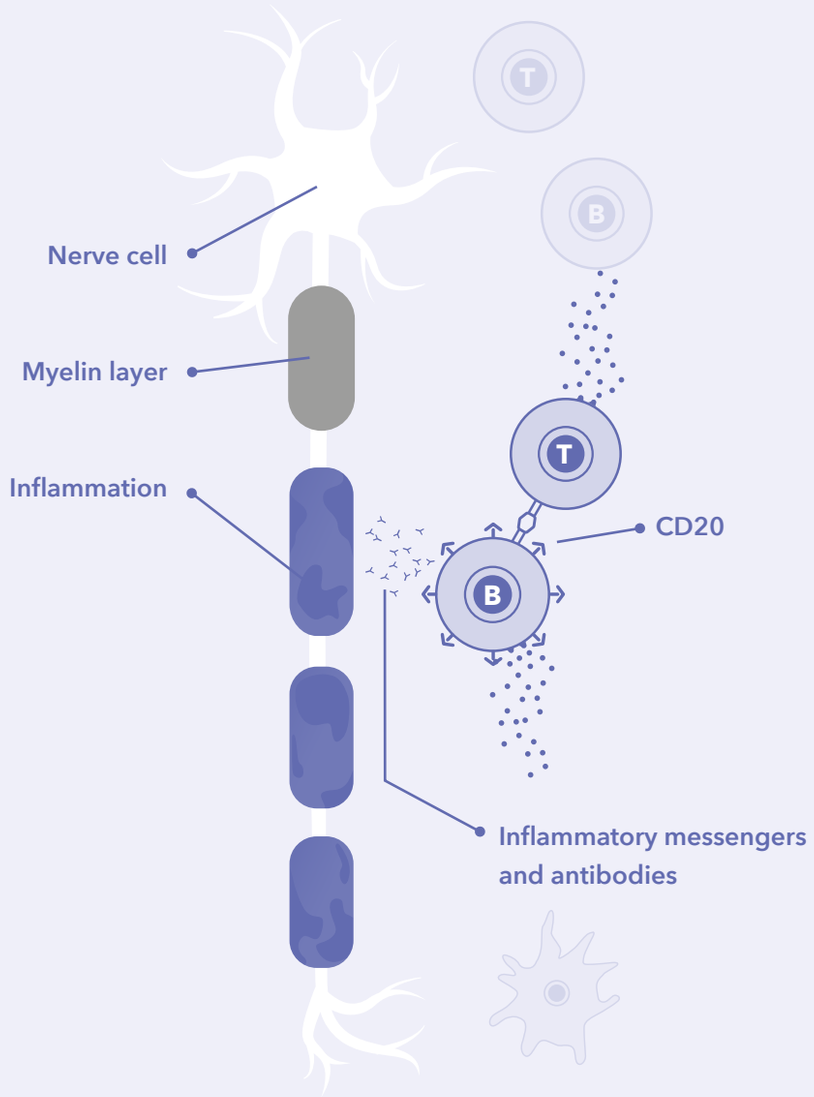
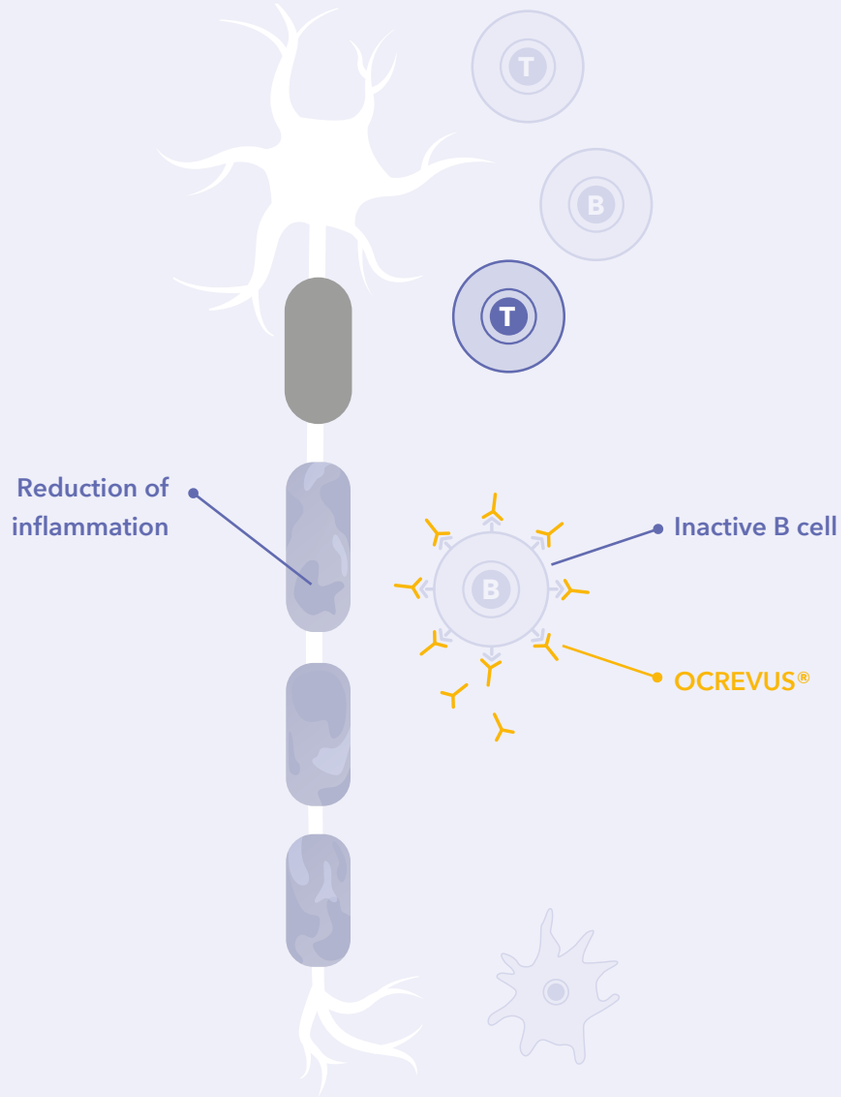
How OCREVUS® works

Misdirected B-cells cause inflammation and damage the myelin



OCREVUS® binds to CD20-positive B cells and reduces inflammation



OCREVUS® I.V. & S.C.

04 MY TREATMENT WITH OCREVUS®

You can receive OCREVUS® as an infusion or as an injection. **Whatever the pharmaceutical form, it is only administered every six months.*** In between, you have application-free time in which you do not have to worry about your therapy. This allows you mental freedom and time for unforgettable moments of life. Discuss with your treatment team which type of administration is most suitable for you.

OCREVUS® can be administered in two ways

OCREVUS® i.v. In the case of infusion, you receive OCREVUS® via a vein (intravenously).

OCREVUS® s.c. In the case of injection, OCREVUS® is injected with a syringe through an extension tube under the skin on the abdomen (subcutaneously).

Both pharmaceutical forms have the same active ingredient; only the route of administration differs.

Plan your arrival and departure for your treatment.
You may be tired afterwards, then it may be better if somebody picks you up or you take a bus, train or taxi home.

	OCREVUS® i.v. Infusion	OCREVUS® s.c. injection
Administration frequency	**Every six months;** only the first dose is given in two separate doses, at an interval of two weeks.	**Every six months;** a minimum interval of five months must be maintained between doses.
Mode of administration	**Intravenous infusion** into an arm vein	**Subcutaneous injection** in the abdomen
Duration of administration	About **2 to 3.5 hours**	**About 10 minutes**
Pretreatment before each administration (premedication)	**One hour** before infusion	**Shortly before** injection
Follow-up observation time	**One hour**	**At least one hour after first injection** For follow-up injections, the follow-up observation time can be shorter or no longer required.
Application by	Healthcare professionals	Healthcare professionals

No special check-ups between treatment sessions are prescribed for either pharmaceutical form. Nevertheless, it is of course good if you regularly visit your doctor for a check. Ask your treatment team how often they want to see you.

Which pharmaceutical form suits you best depends on your personal preferences and your medical needs. Your treatment team can advise you and decide together with you which option is right for you.

* For intravenous administration, the first dose is administered in two separate infusions (two weeks apart). No split of the first dose is required for subcutaneous administration.

My OCREVUS® infusion

If you receive OCREVUS® as an infusion, it is introduced into your bloodstream as a solution. For this purpose, the concentrate is diluted beforehand with an isotonic sodium chloride solution. During the infusion, the medicine slowly passes into your body through a vein. You will receive 600 mg of OCREVUS® solution per infusion. Only at the start of therapy do you not receive the total dose, but two single doses (300 mg each). For this reason, the first administration involves scheduling two infusion appointments at intervals of 14 days, each lasting about 4.5 hours. After the start of therapy, you will always receive OCREVUS® at intervals of six months.

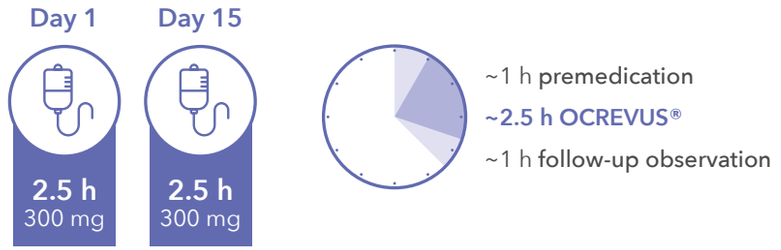
Before the infusion, you will receive a so-called premedication such as methylprednisolone and an antihistamine. This ensures that you tolerate OCREVUS® well. As soon as the premedication takes effect, the OCREVUS® infusion will start.

The total duration of the treatment consists of about one hour of premedication, 2.5 or 3.5 hours (initial or follow-up dose) of infusion, and one hour of follow-up observation. If you did not experience any severe reactions after previous OCREVUS® infusions, the time of administration or infusion of the follow-up dose can be reduced to two hours.

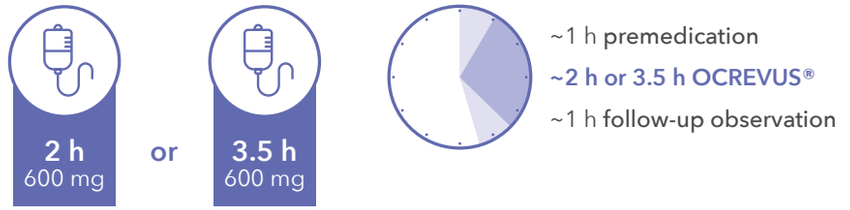
After the infusion is complete, you can go home and have six months of application-free time.

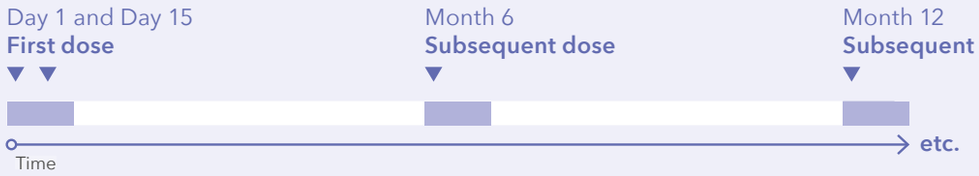
Administration of OCREVUS® i.v.

First dose



Follow-up doses | Every six months





Treatment in everyday life and the day of infusion

Discuss the topics of everyday life that are important for you in terms of treatment with the doctor and the healthcare professionals of the centre. How does the treatment affect my everyday life? Do I have to keep to a particular diet? May I continue to play sports? Can I travel to distant countries? Make yourself a checklist with your questions first.

Discuss with your doctor and healthcare professionals how you can arrange the day before the infusion. They can give you tips for your individual situation.

General recommendations:

- Drink plenty on the day before the infusion, preferably water or unsweetened herbal and fruit tea.
- However, you should avoid alcohol.
- You may go to work as usual in the days before the infusion.
- Even playing sports is not usually a problem.
- Have a normal breakfast on the day of the infusion.

Make your infusion as comfortable as possible

Take drinks and snacks with you. However, check with the healthcare professionals first to see whether this is possible. Time goes faster with a good (talking) book, music, magazines, the tablet or a puzzle book. You may also need a blanket or a neck pillow to make yourself comfortable.

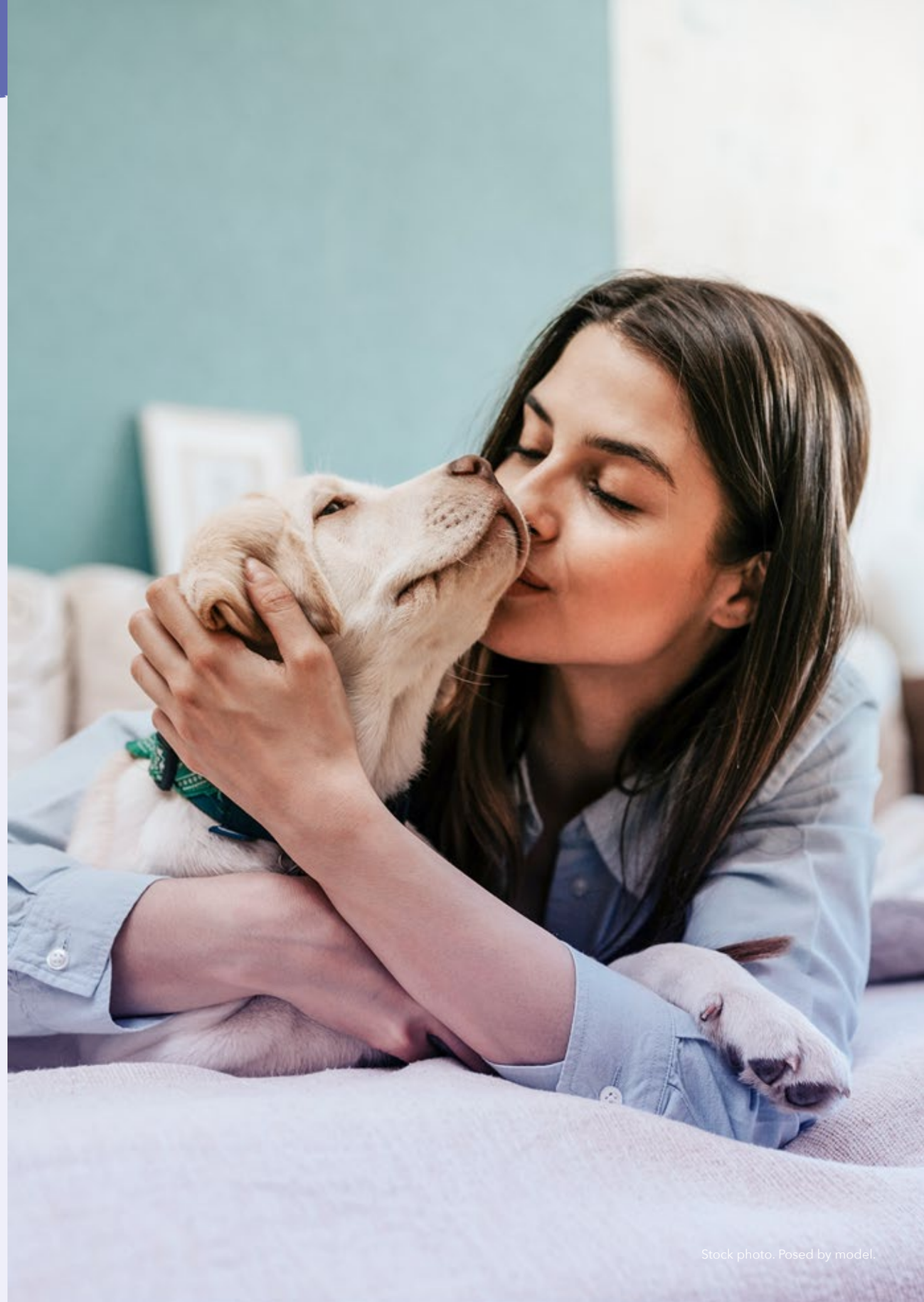
Use the time to get to know others

Talk to other patients, exchange personal experiences.

Gather new strength

You can also take a nap during the infusion time.

Since premedication can make you tired and affect your ability to drive, you should make good arrangements for your travel to and from the place of infusion. Talk to your doctor, healthcare professionals and your contacts in advance.



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My OCREVUS® injection

During the injection, OCREVUS® is injected as a solution under the skin on the abdomen and passes into your bloodstream from there. You will receive 920 mg of OCREVUS® in 23 ml solution per injection. The injection is given by a healthcare professional.

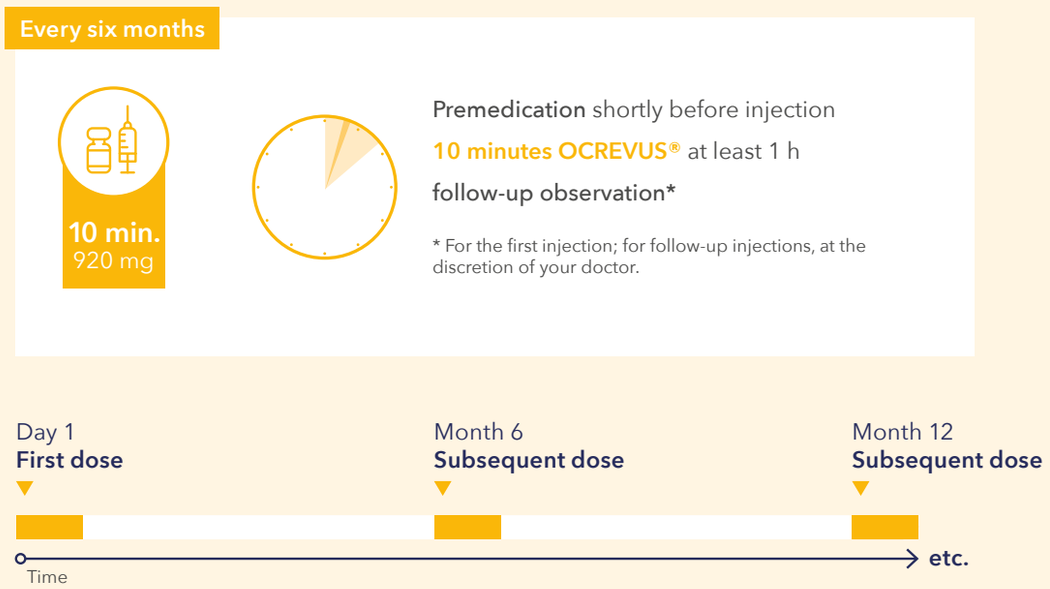
Shortly before your OCREVUS® injection, you will receive a so-called premedication such as dexamethasone and an antihistamine. This ensures that you tolerate OCREVUS® well. The injection itself takes only about 10 minutes. After the first injection, you will remain in the practice or clinic for at least one hour for follow-up observation. For follow-up OCREVUS® injections, your doctor will decide whether and for how long you need to stay for follow-up observation or whether you can go home immediately after the injection. Ask your treatment team how much time you should allow on your treatment day.

Afterwards, you can go home and have six months of application-free time.

Wear appropriate clothing for injection in the abdominal area.
Your clothing should make the abdominal area easily accessible and comfortable. Avoid tight clothing, rigid fabrics and belts to avoid friction and pressure that could irritate the skin. If you get any skin reactions, please contact your treatment team.

Hyaluronidase
In addition to the active ingredient ocrelizumab, the OCREVUS® injection solution contains so-called hyaluronidase. This inactive ingredient makes the injection easier. Hyaluronidase cleaves a part of the supporting tissue under the skin, hyaluronic acid, so that the injection solution can be distributed more easily. The cleavage of hyaluronic acid is only temporary: after one to two days, the original architecture of the supporting tissue under the skin is restored.

Administration of OCREVUS® s.c.



05 POSSIBLE SIDE EFFECTS

Infusion reactions

An infusion of OCREVUS® may result in an infusion-related reaction. In the studies with OCREVUS®, infusion reactions often occurred only during the first infusions and decreased markedly during the further course of therapy. In the vast majority of cases, these were mild to moderate reactions.

Possible symptoms of infusion reactions
Itching, skin rash, hives, redness, throat irritation or sore throat, shortness of breath, respiratory distress, swelling of the throat, redness occurring in sudden attacks, low blood pressure, fever, fatigue, headache, vertigo, nausea, accelerated heartbeat.

Whether you have mild or severe reactions, your treatment team is very knowledgeable and can help you quickly. In most cases, it is sufficient to reduce the infusion rate or to interrupt the treatment for a short time. Before each infusion, you will receive medicines (premedication) that will help you to tolerate the infusion well.

Listen to your body
Please tell your treatment team immediately if you notice any new symptoms during or after treatment with OCREVUS®, even if they seem harmless to you. The team knows exactly what to do.

Injection reactions

An injection of OCREVUS® may result in an injection-related reaction. In the OCREVUS® injection study, injection reactions occurred more frequently after the first injection and decreased during the course of therapy. All injection-related reactions were mildly or moderately pronounced. Injection reactions may be restricted to the injection site (local injection reactions) or may affect the whole body (systemic injection reactions).

Possible symptoms of injection reactions
Local: redness, pain, swelling or itching at the injection site.
Systemic: headache, nausea.

Before each injection, you will receive medicines (premedication) that will help you to tolerate the injection well. However, if injection reactions do occur, your treatment team will know exactly what to do to relieve the symptoms.

Listen to your body
If you notice any signs or symptoms of a reaction to OCREVUS® during administration or for up to 24 hours afterwards, notify your treatment team immediately. It is also best to discuss with your doctor what to do if you notice symptoms in the evening, at night or at the weekend.

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As with any medicinal product, side effects may occur during treatment with OCREVUS®. The most important adverse effects are summarized below. The most commonly reported side effects are infusion or injection reactions and infections.

Dealing with side effects
If you notice any side effects, contact your treatment team immediately. You can also find comprehensive information on this topic in the OCREVUS® package leaflet.

Infections
- (Upper) respiratory tract infection
- Fever and/or chills
- Cough that would not decrease
- Influenza
- Inflammation of the nose and throat (nasopharyngitis)
- Infection of the paranasal sinuses (sinusitis)
- Inflammation of the bronchi (bronchitis)
- Herpes infection (herpes/skin vesicles or shingles)
- Infection of the stomach and bowel (gastroenteritis)
- Viral infection
- Inflammation of the conjunctiva (conjunctivitis)
- Skin infection

PML
Doctors should be alert for early signs and symptoms of progressive multifocal leukoencephalopathy (PML, a very rare life-threatening viral infection of the brain).

The following symptoms may indicate PML:
- Increasing weakness on one side of the body
- Awkwardness of the limbs
- Balance disorders
- Vision disorders
- Change in thinking, memory and orientation

If any such changes appear, consult a doctor immediately.

Other side effects
- Reduction in certain antibodies in the blood that help to protect against infection
- Cough
- Build-up of tough mucus in the nose, throat or chest
- Low count of certain white blood cells (neutropenia)

06 WARNINGS AND PRECAUTIONS

Talk to your doctor or healthcare professional before taking OCREVUS® if any of the following apply to you.

Your doctor may decide to delay the start of treatment with OCREVUS® or not to start treatment if:

You are known to have **another disease that affects your immune system**. Treatment with OCREVUS® may not be a viable option in such cases.

You are suffering from an **infection**. Your doctor will wait until the infection has resolved before you receive OCREVUS®.

You have ever suffered from a liver disease called **hepatitis B** or you are a carrier of the hepatitis B virus.

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Therefore, before treatment with OCREVUS®, your doctor will check:

- Whether you are at risk for hepatitis B infection. A blood test is performed in patients who have suffered from hepatitis B or who are carriers of the hepatitis B virus. You will also be monitored by your doctor for signs of hepatitis B infection. The reason for this is that the virus may become active again and could lead to serious damage to the liver.

- You currently have **cancer** or have had cancer in the past. Your doctor may decide to delay the start of treatment with OCREVUS®.

- You are taking **medicines that suppress or otherwise affect your immune system** – this includes other medicines used to treat MS. There are some medicines that should not be used together with OCREVUS® as the effects on the immune system may be too severe. Your doctor may discuss this with you before starting treatment with OCREVUS®.

If any of the above apply to you (or if you are not sure), talk to your doctor before using OCREVUS®.

Vaccinations

Your doctor will check whether you still need vaccinations or booster vaccinations before starting treatment with OCREVUS®. All vaccinations should have been administered at least six weeks before the start of treatment with OCREVUS®.

Tell your doctor if you have recently received or are planning to receive a vaccine in the near future.

Vaccinations with live vaccines must be carried out only up to six weeks before treatment with OCREVUS® (first dose). The safety of a vaccination with live or live-attenuated vaccines following OCREVUS® therapy has not been studied. Vaccination with live vaccines is not recommended during treatment and until repopulation of B cells.

OCREVUS® and other medicines

Tell your doctor if you are taking or have recently taken or may take any other medicines in the future. In particular, tell your doctor if:

- In the past, present or future, you have used, are using or may use medicines that affect the immune system, e.g. chemotherapy, medicines that suppress the immune system or other treatments for MS.
- You are taking medicines for high blood pressure. In some people, carrying out an infusion can lead to a lowering of blood pressure. Your doctor may ask you to stop taking these medicines 12 hours before each infusion of OCREVUS®.

Pregnancy

Before using OCREVUS®, tell your doctor if you are pregnant, may be pregnant or are planning to have a baby.

OCREVUS® can pass through the placenta and affect your baby. Do not use OCREVUS® during pregnancy unless you have discussed this with your doctor. Your doctor will work with you to evaluate the benefit of treatment with OCREVUS® against the possible risk to your unborn child.

Contraceptive measures for women

Reproductive female patients must use an effective method of contraception:

- During treatment with OCREVUS®
- For another six months after their last OCREVUS® infusion

Breast-feeding

You should not breast-feed during treatment with OCREVUS®. OCREVUS® can be excreted in breast milk.

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07 THE MOST BURNING QUESTIONS

Can I go on holiday while taking OCREVUS®?

Yes, you can enjoy your holiday away from home to the fullest. However, please keep in mind your OCREVUS® administration plan.

If you have a certain period of time in the year in which you are always on holiday or have other fixed plans, your treatment can be planned so as to avoid this period. Ask your MS treatment team to consider this when planning your next dose of OCREVUS®.

However, if you need **travel vaccinations** for your holiday, you should have them done at least **six weeks before starting** your next treatment with OCREVUS®.

You should **NOT receive live vaccines** or live-attenuated vaccines while receiving OCREVUS®. Always talk to your MS treatment team before agreeing to travel vaccinations or seasonal vaccinations.

What happens if I forget a dose?

Please do not make any decisions to change your treatment plan without first consulting your MS treatment team. If you cannot attend a treatment appointment for personal reasons, please inform your MS treatment team in good time. They will advise you on how to proceed in such situations.

If you have missed an appointment, please contact your MS treatment team to arrange a replacement appointment as soon as possible. **Do not wait until the next scheduled dose.**

It is important that you receive OCREVUS® as prescribed by your doctor to ensure that your MS is controlled in the best possible way. OCREVUS® should be administered every six months (with a minimum interval of five months between doses).

Can I play sports while receiving OCREVUS®?

Yes! There is no reason why you should not play sports while you are receiving OCREVUS®. In fact, exercise has benefits for mental and physical health of every person.

Exercise not only improves general fitness, but also muscle strength and balance and reduces fatigue. This can make you feel better in general.

How do I know that OCREVUS® works?

OCREVUS® aims to reduce the inflammatory activity of your MS, including the likelihood of a relapse, and to slow down the progression of your MS.

Your doctor will regularly check whether your treatment takes effect by checking:

- Whether and how many relapses you had
- How severe the relapses were
- The number of lesions to be seen on your medical scans
- Changes to your physical and mental abilities

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OCREVUS® I.V. & S.C.

08 OCREVUS® OVERVIEW

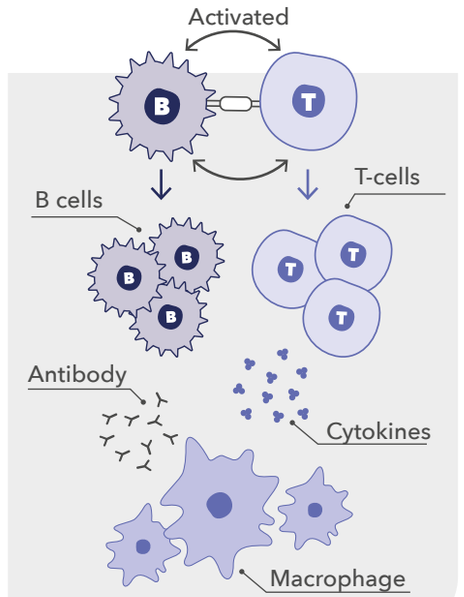
Key points about the mechanism of action

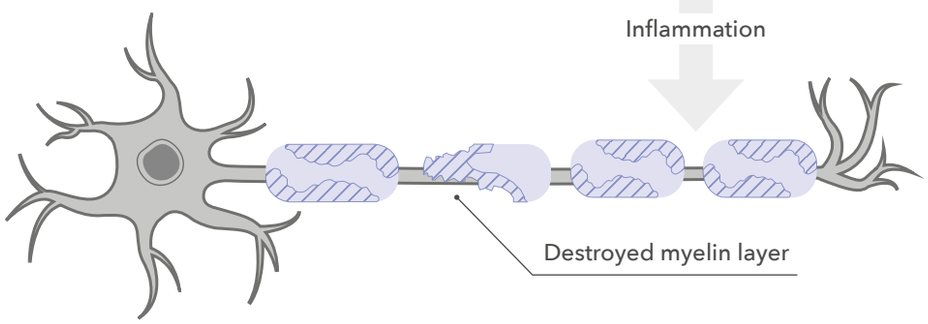
OCREVUS® is approved for the treatment of people with relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). You can find out exactly how OCREVUS® works here.

Misdirected B and T cells

B cells play a decisive role in the destruction of the myelin sheaths. B cells and T cells stimulate each other and release pro-inflammatory cytokines.

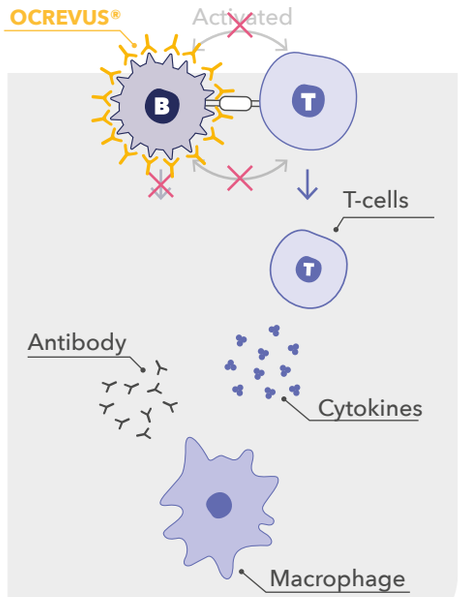
This attracts macrophages that attack the myelin sheaths. The misdirected B cells also produce antibodies that intensify the inflammatory process. MS progresses.

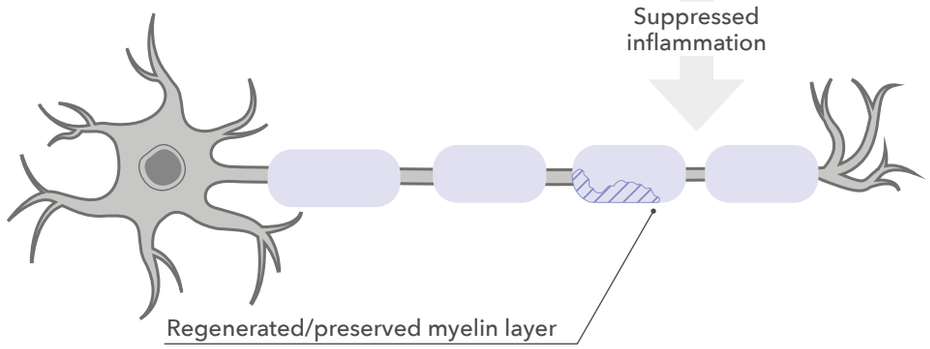




OCREVUS® removes B cells

The misdirected B cells carry the protein CD20 on their surface. OCREVUS® binds specifically to B cells that carry the protein CD20 on their surface and renders them harmless. The CD20-positive B cells disappear, and pro-inflammatory substances are released only to a lesser extent. The myelin can recover. The progenitors of B cells and the existing protection by antibodies are not impaired. Thus, the defence of the immune system against infection is largely preserved.





Key points about the administration

You can receive OCREVUS® as an infusion or injection. Both pharmaceutical forms have the same active ingredient. Ask your MS treatment team if you are not sure which pharmaceutical form you are going to receive.

Every six months

To get the most out of OCREVUS®, you should keep to the six-month interval. In between, you have application-free time* and do not need to think about your MS therapy.

	OCREVUS® i.v. Infusion	**OCREVUS® s.c. injection**
Administration	Infusion into an arm vein	Injection under the skin on the abdomen
Treatment process	~1 h premedication **~2 h to 3.5 h OCREVUS®** ~1 h follow-up observation	Premedication shortly before **10 minutes OCREVUS®** at least 1 h follow-up observation**
Administration by healthcare professionals	In the reclining chair. An infusion bag with an attached tube is fixed to an infusion stand. The tube is connected to a needle that is inserted into a vein of the hand.	Half-lying on the back or on the side. The syringe is connected to a tube with a needle («butterfly») that is inserted into the skin of the abdomen.
Possible side effects	**Infusion reactions** Itching, skin rash, hives, redness, throat irritation or sore throat, shortness of breath, respiratory distress, swelling of the throat, redness occurring in sudden attacks, low blood pressure, fever, fatigue, headache, vertigo, nausea, accelerated heartbeat	**Injection reactions** **Local:** redness, itching, pain or swelling at the injection site **Systemic:** headache, nausea
	Infections, reduction of certain antibodies in the blood, build-up of tough mucus in the nose, throat or chest, low white blood cell count (neutropenia)	

* In the case of intravenous administration, the first dose is administered in two separate infusions (at a two-week interval). In the case of subcutaneous administration, it is not required to split the first dose. ** For follow-up injections, the follow-up observation time can be shorter or no longer required.

Stock photo. Posed by model.

OCREVUS® I.V. & S.C.

09 GLOSSARY OF THE MOST IMPORTANT TERMS

Even a patient brochure does have some medical language. Perhaps you stumbled upon one or the other «foreign word» while reading the brochure. Therefore, you will find the important medical terms in alphabetical order explained in simple terms once again.

Medical history:
Collection of the information on the (previous) history of a disease.

Antibodies (defensive substances):
Proteins that are part of the immune system and play an important role in the defence against foreign substances such as pathogens. If the antibody is directed against the body's own structures, it is called an autoantibody.

Autoimmune disease:
Reaction of the immune system to the body's own cells or tissues. In principle, this can affect any part of the body can be affected. In MS, the myelin sheaths of the nerve pathways are attacked. In other autoimmune diseases such as autoimmune hepatitis, the liver is attacked; in type 1 diabetes, the cells of the pancreas become the target.

B cells (B lymphocytes):
A subgroup of white blood cells (lymphocytes). They are produced in the bone marrow («B» stands for «bone marrow») and are transformed into plasma cells after contact with the pathogen. In turn, plasma cells produce antibodies against this pathogen. This deactivates the pathogen.

Diagnosis:
Identification of a disease and its designation with the corresponding (scientific) name.

Evoked potentials:
A diagnostic method which measures the electrical currents in the brain triggered by a particular stimulus and thus investigates the functionality of the nerve pathways.

Fatigue (French: tiredness, exhaustion):
Symptoms that accompany various chronic diseases (often MS) and describe severe exhaustion.

Immune system (defence system):
All tissues and cells of the body that help to combat pathogens such as viruses and bacteria. T cells and B cells are important components of the immune system. In addition to these important components, it also includes some organs and tissues, such as the spleen or bone marrow.

infusion:
Administration of a medicine in liquid form through a vein.

Lesion:
In the case of MS, a tissue site damaged by inflammation.

Spinal fluid (cerebrospinal fluid):
Fluid that flows around the brain and spinal cord and protects them from external influences.

CSF diagnostics:
Investigation of the cerebrospinal fluid.

Lumbar puncture:
A method for obtaining cerebrospinal fluid. A special hollow needle is inserted between the vertebrae to collect cerebrospinal fluid and investigate it in a laboratory.

Magnetic resonance imaging (MRI):
Graphic representation of the internal parts of the body using magnetic fields and radio waves. MRI provides very accurate images and thus makes even the smallest areas of inflammation and damage visible. Another advantage is that, unlike X-ray examinations, MRI does not use X-rays, so the patient is not exposed to radiation.

Monoclonal antibodies:
Highly specialised and targeted defensive substances that are synthetically manufactured using biotechnological processes. These substances are able to activate natural defences of the body against a disease.

Multiple sclerosis (MS):
Inflammatory disease of the central nervous system, when numerous different (multiple) inflammatory foci can be hardened by the formation of scar tissue (sclerosis).

Myelin/myelin sheath:
A protein-bound fat-like substance that surrounds the nerve fibres like an insulating layer and provides for the transmission of signals.

Oligoclonal bands:
Enrichment of certain proteins that can be seen in the form of bands (strips) in the laboratory. If they occur in the cerebrospinal fluid, this can be an indicator of MS.

Plasma cells:
Mature B cells that are able to produce protective antibodies. The antibodies can be used for targeted destruction of the pathogens that have entered the body.

PPMS (primary progressive MS):
The rarest form of MS, which occurs in 10 to 15 percent of patients and is characterized by continuous deterioration. The damage or loss of function that occurs cannot be repaired anymore.

Premedication (previous medication):
Administered in the form of tablets or infusions before the actual infusion. These medicines counteract infusion-related and injection-related symptoms.

Progression:
Persistent increase in symptoms (without regression). This may happen gradually (in stages) or when the increased symptoms persist after a relapse.

Remission:
The state of disease after a relapse in which neither the doctor nor the patient can identify any disease activity. However, remission does not mean that the patient has been cured. After a relapse, the symptoms can regress completely (complete remission) or some recognisable damage may remain (incomplete remission).

RRMS (relapsing remitting MS):
The most common form of MS, which affects 80 percent of patients. The disease progresses in relapses. After a relapse, the symptoms regress completely or at least in part.

Relapse:
Recurrence of signs of disease after a relatively long pause (at least 30 days) and after a more or less complete regression of symptoms.

SPMS (secondary progressive MS):
The second stage of the disease, which around 50 percent of patients develop. The symptoms increase continuously: in some patients, by relapses; in others, no distinct relapses can be seen.

Stem cells:
Body cells that can develop into different cell types or tissues.

T cells (T lymphocytes):
A subgroup of white blood cells (lymphocytes). They mature in the thymus (hence T lymphocytes) and, after contact with a pathogen, form messengers that lead to defence reactions and thus destroy the harmful cell.

White blood cells (leukocytes):
Part of the immune system and important components of the immune defence.

Central nervous system (CNS):
Collective term for the brain and spinal cord. As the control centre, it transmits and receives signals from the body, including organs and muscles, via the nerve pathways.

10 USEFUL ADDRESSES IMPORTANT INFORMATION

Humans in Focus
A website with helpful information

The diagnosis of multiple sclerosis is a major challenge not only for those affected, but also for their families and friends. Here you will find answers and assistance that can help you make things easier with your condition.

You can reach the website directly via this QR code:
www.roche-fokus-mensch.ch/ms/multiple-sklerose

FokusMe
The app for networking

- **Connect with other affected persons, relatives and healthcare professionals**
- **Current news of therapy**

Use the QR codes to download the app directly from the App Store or Google Play Store:

App Store

Google Play Store

For more information, please visit:
www.focusme.health

MedWallet
Your digital patient pass

All important information about your treatment with OCREVUS® in digital form in your mobile phone.

- **Schedule your appointments in the app.**
- **Receive SMS reminders of upcoming appointments.**
- **Record your medicines and accompanying medicines in this app.**

Use the QR codes to download the app directly from the App Store or Google Play Store:

App Store

Google Play Store

After downloading and opening the MedWallet app, you will be asked to enter a code. You can get the corresponding QR code or code for the product from your MS treatment team.

THE REPORTING OF SIDE EFFECTS

If you notice any side effects, please contact your doctor, healthcare professional or pharmacist. This also applies to side effects that are not listed in this brochure or the package leaflet. By reporting side effects, you can help to improve knowledge about the tolerability and use of medicines. You can report side effects online as follows:

Pharmacovigilance forms
at www.swissmedic.ch

You can find more information about multiple sclerosis here:
https://roche-fokus-mensch.ch/ms/multiple-sklerose

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