

Getting to know KESIMPTA® (ofatumumab)

This booklet is intended for patients who have been prescribed of atumumab.

Reporting of side effects:

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack.

The medicine referred to in this material 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. Please see www.mhra.gov.uk/yellowcard (UK) for instructions on how to report side effects.

This leaflet has been developed and funded by Novartis Pharmaceuticals UK Limited.

This booklet should not replace the information shared to you by your nurse or pharmacist or within the packaging information.

U NOVARTIS

Your journey with ofatumumab

You have been prescribed of a tumumab to treat your multiple sclerosis (MS). This booklet explains a bit more about your treatment.

The package leaflet that comes with your medicine also contains important information that you should read carefully and keep handy for future reference.

As with any medicine, the more you know about how it works and what to expect, the more confident and prepared you can feel when you start to take it.



Scan this QR code or visit www.health.novartis.co.uk/public/ medicines/neuroscience/kesimpta/ patient-resources-and-support for further resources and support.

Ask your doctor or nurse if you have any further questions about MS or ofatumumab.



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About your medicine and MS

What is ofatumumab and what is it used for?

Ofatumumab is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.Ofatumumab is made of a type of molecule (monoclonal antibody) called ofatumumab, and is intended for you to administer yourself once-monthly as a subcutaneous (under the skin) injection.^{1,2}

-Demyelination by immune cells

The myelin coating that protects your nerves gets damaged (demyelination).

What is MS?

MS is a long-term autoimmune disease where your immune system mistakenly attacks your central nervous system. When the attack happens, the immune system targets the coating that protects the nerves around your brain and spinal cord (called the myelin sheath). This covering is there to protect your nerves and help messages travel along them. When myelin is damaged (called demyelination) messages don't pass along your nerves as efficiently as they used to, so messages can be delayed or sometimes may not get through at all. These areas of damage are called lesions and they cause the symptoms you experience.³

There are three main types of MS: relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS). RRMS involves episodes of relapses (flare-ups) and subsequent complete or partial remission (disappearance/lessening of symptoms). This medicine is used to treat RMS.⁴

How does your medicine work?

Ofatumumab works by removing B cells that circulate in the body. B cells are a type of white blood cell that form part of the immune system (the body's defence system). In MS, the immune system attacks the protective layer around nerve cells; B cells are involved in this process. Ofatumumab targets certain B cells by attaching to a protein called CD20 on their surface. Removing these CD20-positive B cells reduces the chance of a relapse, relieves symptoms and slows down the progression of the disease.¹²

Do not take your medicine:²

- If you are allergic to ofatumumab or any of the other ingredients of this medicine (L-arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid [for pH adjustment] and water for injections).
- If you have been told that you have severe problems with your immune system.
- If you are suffering from a severe infection.
- If you have cancer.

Warnings and precautions²

Talk to your doctor or nurse before using ofatumumab.

- Ofatumumab may cause the hepatitis B virus (HBV) to become active again.
 Your doctor will perform a blood test to check if you are at risk of hepatitis B infection. If this shows that you have had hepatitis B or are a carrier of the HBV, your doctor will ask you to see a specialist.
- Before you start treatment your doctor may check your immune system.
- If you have an infection, your doctor may decide that you cannot be given of atumumab or may delay your treatment until the infection is resolved.
- Your doctor will check if you need any vaccinations before you start your treatment. If you need a type of vaccine called a live or live-attenuated vaccine, it should be given at least 4 weeks before you start treatment. Other types of vaccines should be given at least 2 weeks before you start ofatumumab treatment.

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Receiving and storing of atumumab

Please refer to the package leaflet that came with your medicine for further information.

With your hospital team, you will decide how you will receive your medicine. It can be delivered to your door or collected from your hospital or pharmacy.

How should I store of atumumab?²

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C - 8°C). Do not freeze.

If necessary, ofatumumab may be stored unrefrigerated for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, ofatumumab can then be returned to the refrigerator for a maximum of 7 days.

Keep the pre-filled pen in the outer carton in order to protect from light.

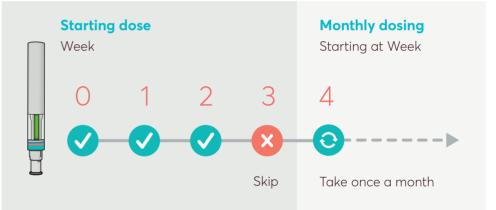
Taking your medicine

Your dosing schedule²

The initial dosing is 20 mg of atumumab administered on the first day of treatment (Week 0) and after 1 and 2 weeks (Week 1 and Week 2). After these first 3 injections, there is no injection in the following week (Week 3).

Starting at Week 4 and then every month, the recommended dose is 20 mg of atumumab.

Once you start treatment, taking ofatumumab can be straightforward to fit into your routine. Try to take it on the same date every month, for example the 5th of every month (or any date that would be easy for you to remember).



Quick fact:

Forgot a dose in your first month?

Do not wait until your next scheduled dose, instead administer your dose as soon as you remember and time your future injections from the day you injected this dose.



Using your ofatumumab pen



Take pen out of the fridge 15 to 30 minutes before injection to allow it to reach room temperature. Look through the viewing window. Do not use if the liquid has visible particles or is cloudy. The liquid should be clear to slightly opalescent and colourless to slightly brownish-yellow. You may see a small air bubble, which is normal. Check the expiry date of the pen (found on the outer carton or the label on the pen), do not use if the pen has expired. Contact your pharmacist or healthcare professional if your pen fails any of these checks. Make sure you have an alcohol wipe and cotton ball/gauze to hand.²



Pick and clean your injection site. Please see page 9 for help picking an injection site. Wash your hands with soap and water. Using a circular motion, clean the injection site with the alcohol wipe. Let it dry completely. Do not touch the injection site again before injecting.²



Remove the cap and throw it away. Twist off the cap in the direction of the arrow. Don't try to reattach it. Make sure you use the pen within 5 minutes of removing the cap and do not shake. You may see a few drops of medicine come out of the needle. This is normal.²



Hold the pen at a 90° angle to the cleaned injection site. **Press down** to activate the pen and **hold**. You'll hear the first click and the green indicator will start moving.²



Watch the green indicator fill and listen for the second click to signal you're almost done. Once the green indicator is full and has stopped, you'll know that you've done it right. If there's blood at the injection site, press down with the cotton ball/gauze, but don't rub. If the green indicator does not fill the window, this means you have not received the full dose. Contact your doctor or pharmacist if the green indicator is not visible.²



Dispose of the used pen in a sharps bin (i.e. a puncture-resistant closable container or similar), if provided. Please ask your doctor or pharmacist for more information on how to dispose of your used pens safely. Keep the sharps container out of the reach of children. Never try to re-use your pen. Do not throw away any medicines via wastewater or household waste (including flushing down the toilet or putting down the sink).²

Choosing the appropriate spot

The outer upper arm may be used by a healthcare professional or caregiver if they are injecting you.²

The front of the thigh is the **recommended** site.²

Choose a different site each time an injection is given. The lower abdomen (stomach area) except the area 5 cm around your

belly button.²

Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars, stretch marks or infection sites.²

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Important safety information

Do not use this medicine:²

- If either the seal on the outer package or the seal on the pen is broken. Keep the pen in the sealed outer package until you are ready to use it.
- If you drop your pen and it looks damaged or if you dropped it with the cap removed.
- After the expiry date, which is stated on the outer box or the label on the pen after 'EXP'. The expiry date refers to the last day of that month.
- If the solution contains visible particles or is cloudy.

You should make a note of when and where on your body you inject your medicine. There's a handy tracker at the back of this book for you to use to do this.

Things to be aware of

Can I take other medications while being treated with ofatumumab?²

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist:

- If you are taking, have recently taken or may take any other medicines that affect the immune system. This is because these may have an added effect on the immune system.
- If you plan to have any vaccinations.

While using ofatumumab tell your doctor:²

 If you have a general injection-related reaction or a local injection-site reaction. These are the most common side effects of ofatumumab treatment. They usually occur in the 24 hours after ofatumumab is injected, in particular after the first injection. The first injection should take place under the guidance of a healthcare professional.

- If you have an infection. You may get infections more easily or an infection you already have may get worse. This is because the immune cells that ofatumumab targets also help to fight infection. Infections could be serious and sometimes even life-threatening.
- If you plan to have any vaccinations. Your doctor will tell you whether the vaccination you need is a live vaccine, a live-attenuated vaccine, or another type of vaccine. You should not be given live or live-attenuated vaccines during treatment with ofatumumab as this may result in infection. Other types of vaccines may work less well if they are given during treatment with ofatumumab.
- If you think your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms, **tell your doctor straight away**. These effects may indicate a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is caused by a virus infection.



Can I take my medicine if I have recently had a vaccination?²

If you need a type of vaccine called a live or live-attenuated vaccine, this should be given at least 4 weeks before you start treatment with ofatumumab. It is not recommended you receive live or live-attenuated vaccines while you are being treated with ofatumumab or until your doctor tells you that you can. Whenever possible, you should receive other types of vaccines at least 2 weeks before you start treatment with ofatumumab.

 The COVID-19 vaccinations available for use in the UK are messenger ribonucleic acid (mRNA) vaccinations or viral vector vaccinations. Some vaccines may work less well if they are given during treatment with ofatumumab. You should speak to your doctor about whether you should have a COVID-19 vaccination and the timing of this vaccination.^{2,5,6}

Can I take my medicine while pregnant or breast-feeding?²

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 using this medicine.

You should avoid becoming pregnant while using ofatumumab and for 6 months after you stop using it.

If there is a possibility that you could become pregnant you should use an effective birth control method during treatment and for 6 months after stopping of atumumab. Ask your doctor about the options available to you.

If you do become pregnant or think you may be pregnant during treatment or within 6 months after the last dose of ofatumumab, tell your doctor straight away. Your doctor should report your pregnancy to Novartis. Your doctor will discuss with you the potential risks of ofatumumab on pregnancy. This is because ofatumumab can reduce the number of immune cells (B cells) in both the mother and the unborn baby.

Ofatumumab can pass into breast milk. Talk to your doctor about benefits and risks before breast-feeding your baby while using ofatumumab.

Vaccination of newborn babies²

Ask your doctor or pharmacist for advice before vaccinating your newborn baby if you have used ofatumumab during your pregnancy.

Side effects that some people may get with ofatumumab

Like all medicines, ofatumumab can potentially cause side effects in some people.

It is important to be aware of these before you start your medicine. Your doctor, nurse or pharmacist will be able to provide more information if you would like to discuss these.

The most common symptoms that you may experience, which may affect more than 1 in 10 people:²



Upper respiratory tract infections with symptoms such as sore throat and runny nose.



Injection-related symptoms such as fever, headache, muscle pain, chills and tiredness. These usually occur in the 24 hours after an injection of ofatumumab, in particular after the first injection.



Injection-site reactions. Symptoms include redness, pain, itching and swelling at the injection site.



Urinary tract infections.

Common side effects that may affect up to 1 in 10 people include:²



A decrease in the blood level of a protein called immunoglobulin M, which helps protect against infection.



Oral herpes.



Nausea and vomiting (have been reported in association with injection-related reactions).

It is important you tell your doctor, pharmacist or nurse if any of these side effects become severe.

Additional considerations to be aware of:^{1,2}



Weakened immune system. If you are already taking medicines that weaken the immune system, taking ofatumumab before or after those medicines may increase your risk of getting infections.



Infections. If you have an active infection, your doctor should delay your treatment with ofatumumab until your infection is gone.



HBV reactivation. If you have ever had an HBV infection, it may become

active again during or after treatment with ofatumumab (reactivation). Before starting your medicine, your doctor will do a blood test to check for HBV.

If you have any concerns related to safety, please speak to your doctor or nurse in the first instance.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/.

By reporting side effects, you can help provide more information on the safety of this medicine.

7 Wellbeing

Travelling with your medicine: A guide to managing your MS and treatment away from home

We all enjoy the freedom of travel, but when you have a medicine to think about, it can take a bit of forward planning. That's why this chapter includes tips on how to travel with your medicine and ensure that it's stored properly while you're away.

There is also a checklist of things to do before you go. By planning ahead and ensuring you have everything you need, you can make sure your time away goes as smoothly as possible.

Quick facts²

- While travelling (and in general), your medicine should be kept cool (between 2°C and 8°C).
- Do not freeze your medicine.
- If necessary, ofatumumab may be stored unrefrigerated for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, ofatumumab can then be returned to the refrigerator for a maximum of 7 days.

Tips for travelling

For longer trips

- Talk to your doctor ahead of time and arrange to take enough medicine with you to ensure you do not miss any of your scheduled doses.
- Talk to your pharmacist to make sure you have all of the materials that you will need to administer your injections (e.g. cotton balls/gauzes, alcohol wipes).

Your accommodation

- Ring ahead to your holiday accommodation to check that there is a fridge available for you to use and ask them to turn it on before you arrive.
- Remember, if necessary, ofatumumab may be stored unrefrigerated for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, ofatumumab can then be returned to the refrigerator for a maximum of 7 days.
- Most hotels or apartments will be able to provide this free of charge.

Checklist

A few weeks before you travel

Ask your doctor to request a signed letter or a copy of your prescription to confirm that you are travelling with ofatumumab that has been prescribed for you.

Ensure you have enough of atumumab for the length of your trip.

Ring your place of accommodation to check that there is a refrigerator available for you to use a couple of days before you travel. Remember, if necessary, ofatumumab may be stored unrefrigerated for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, ofatumumab can then be returned to the refrigerator for a maximum of 7 days.

Put cotton balls/gauze and alcohol wipes into your travel pack. You will need these for your injection in addition to your ofatumumab pen.

Before you leave home

Make sure you have your signed letter from your doctor or a copy of your prescription.

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Frequently asked questions

What should I do if I forget an injection? If you have forgotten an injection of ofatumumab, inject yourself as soon as possible. Do not wait until the next scheduled dose. The timing of future injections should then be calculated from the day you injected this dose and not based on the original schedule.²

What should I do if I administer a dose before my scheduled injection date? If you have injected more of atumumab than you should or you've injected it sooner than the instructions on your doctor's prescription say you should, speak to your doctor as soon as possible.²

What should I do if the ofatumumab pen doesn't work? If you think your pen is not working correctly or are unsure whether you have correctly injected using the pen, please contact your doctor or pharmacist.²

What should I do if I stop using of atumumab? Do not stop using of atumumab or change your dose without talking with your doctor. Some side effects can be related to a low level of B cells in your blood. After you stop treatment with of atumumab, your blood level of B cells will gradually increase to normal. This can take several months. During this time, some side effects described in this leaflet may still occur.²

What should I do if there is a spot of blood at the injection site? There may be a small amount of blood at the injection site. You can press a cotton ball/gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.²

How will I know if my medicine is working? ofatumumab has been shown in studies to reduce the number of relapses and slow progression of the disease in patients with RMS. It is important you discuss your symptoms or any concerns with your doctor, nurse or pharmacist.²

Contact information

Always contact your doctor, nurse or local community pharmacist if you have any questions about your prescription, medicine or you would like any other advice.

My healthcare team's contact details:

Any other notes

Contacts for further information

You may find some more useful information at the following websites:



Multiple Sclerosis Trust

UK charity entirely focused on MS, providing information, resources and support. **mstrust.org.uk**



MS

MS Society

UK charity entirely focused on MS, providing information, resources and support. **mssociety.org.uk**

Shift.ms

International charity and digital community for people diagnosed with MS. Talk to others who understand. **Shift.ms**

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Using this diary



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To ensure you are getting the most out of your of atumumab treatment, it is important that you follow your dosing schedule exactly as prescribed and as laid out in the Patient Information Leaflet included in your package of of atumumab.

This diary can help you keep track of your injection schedule and appointments. It also includes pages for you to make a note of your symptoms and how you are feeling on a monthly basis.

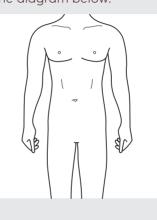
This diary is to help you, you are not required to share it with your doctor. However, the notes you make will help you remember how you have been feeling when you are talking to your doctor.

Injection diary

Week 0 (Dose 1)

Date:

Where did I inject myself? Circle your injection site on the diagram below.



record to speak to my doctor or nurse about?

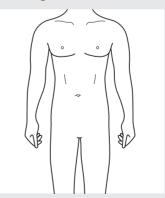
Did I notice anything I want to

How am I feeling?

Week 1

Date:

Where did I inject myself? Circle your injection site on the diagram below.

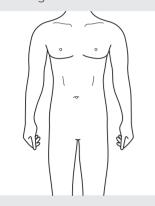


Did I notice anything I want to record to speak to my doctor or nurse about?

Week 2

Date:

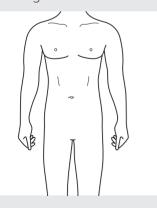
Where did I inject myself? Circle your injection site on the diagram below.



Week 4 (Month 1)

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

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Did I notice anything I want to record to speak to my doctor or nurse about?

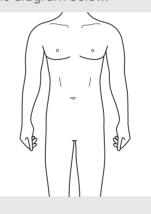
How am I feeling?

Injection diary

Month 2

Date:

Where did I inject myself? Circle your injection site on the diagram below.



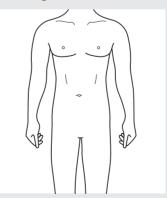
Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Month 3

Date:

Where did I inject myself? Circle your injection site on the diagram below.

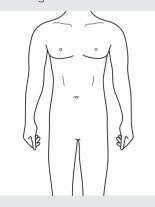


Did I notice anything I want to record to speak to my doctor or nurse about?

Month 4

Date:

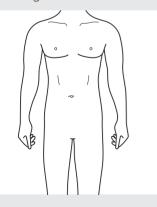
Where did I inject myself? Circle your injection site on the diagram below.



Month 5

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Did I notice anything I want to record to speak to my doctor or nurse about?

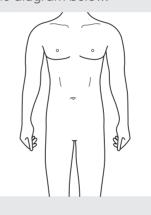
How am I feeling?

Injection diary

Month 6

Date:

Where did I inject myself? Circle your injection site on the diagram below.



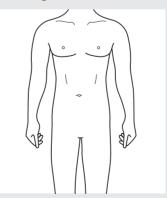
Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Month 7

Date:

Where did I inject myself? Circle your injection site on the diagram below.

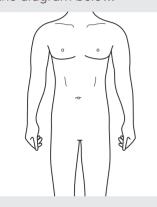


Did I notice anything I want to record to speak to my doctor or nurse about?

Month 8

Date:

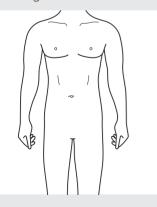
Where did I inject myself? Circle your injection site on the diagram below.



Month 9

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Did I notice anything I want to record to speak to my doctor or nurse about?

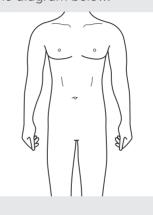
How am I feeling?

Injection diary

Month 10

Date:

Where did I inject myself? Circle your injection site on the diagram below.



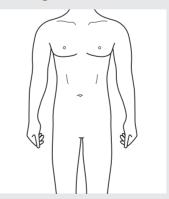
Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Month 11

Date:

Where did I inject myself? Circle your injection site on the diagram below.

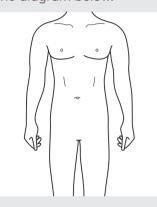


Did I notice anything I want to record to speak to my doctor or nurse about?

Month 12

Date:

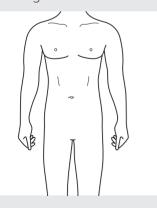
Where did I inject myself? Circle your injection site on the diagram below.



Month 13

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Did I notice anything I want to record to speak to my doctor o

record to speak to my doctor or nurse about?

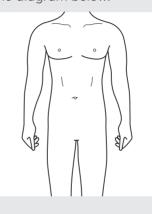
How am I feeling?

Injection diary

Month 14

Date:

Where did I inject myself? Circle your injection site on the diagram below.



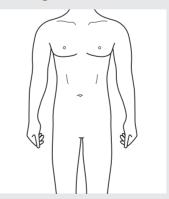
Did I notice anything I want to record to speak to my doctor or nurse about?

How am I feeling?

Month 15

Date:

Where did I inject myself? Circle your injection site on the diagram below.

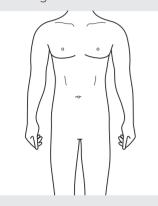


Did I notice anything I want to record to speak to my doctor or nurse about?

Month 16

Date:

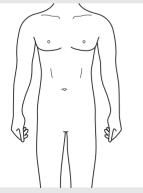
Where did I inject myself? Circle your injection site on the diagram below.



Month 17

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

Did I notice anything I want to

record to speak to my doctor or

How am I feeling?

How am I feeling?

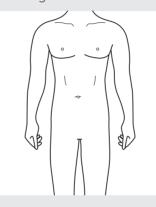
nurse about?

Injection diary

Month 18

Date:

Where did I inject myself? Circle your injection site on the diagram below.



Did I notice anything I want to record to speak to my doctor or nurse about?

Antibodies

A part of your immune system that sticks to bacteria and viruses and attacks them. Antibodies are also sometimes called immunoglobulins.

Autoimmune diseases

Where the immune system targets the body's own components (e.g. cells) by mistake. These diseases are usually treated with medicines that change or reduce the immune response. MS is an autoimmune disease.

B cells

A part of your immune system that abnormally trigger inflammation and cause damage to the central nervous system during active MS.

HBV (hepatitis B virus)

A virus that is spread through blood and body fluids and causes hepatitis B, which can cause serious liver disease.

Immunoglobulin

A part of your immune system that plays an important role in fighting and destroying bacteria and viruses. If you have low immunoglobulins, it means you may have fewer antibodies.

Inflammation

Swelling caused by an immune response that is generally painful, red and hot to touch.

Live or live-attenuated vaccines

Live vaccines contain a weak (or attenuated) form of the germ that causes a disease. Because these vaccines are very similar to the natural infection that they help prevent, they can create a strong immune response.

Monoclonal antibodies

Molecules made in the laboratory that can mimic or enhance the immune system's attack on MS.

MS (multiple sclerosis)

A long-term autoimmune condition where something goes wrong with the immune system and it mistakenly attacks the protective layer that surrounds and protects the nerves around the brain and spinal cord, called the myelin sheath. These areas of damage are called lesions and cause MS symptoms.

Ofatumumab

Ofatumumab is the brand name for ofatumumab (the scientific name).

RMS (relapsing forms of MS)

A type of MS where people have attacks of new and old symptoms, called a relapse.

Subcutaneous injections

These are injections that are administered underneath the skin.

Wastewater

This is 'used' water from any domestic, industrial, commercial or agricultural activities. This includes toilet water and sink water.



Notes	Notes



References:

- 1. KESIMPTA (ofatumumab) Summary of Product Characteristics.
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