Package leaflet: Information for the patient

Kesimpta 20 mg solution for injection in pre-filled pen
ofatumumab

▼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. See the end of section 4 for how to report side effects.

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

What is in this leaflet

1. What Kesimpta is and what it is used for
2. What you need to know before you use Kesimpta
3. How to use Kesimpta
4. Possible side effects
5. How to store Kesimpta
6. Contents of the pack and other information

1. What Kesimpta is and what it is used for

What Kesimpta is
Kesimpta contains the active substance ofatumumab. Ofatumumab belongs to a group of medicines called monoclonal antibodies.

What Kesimpta is used for
Kesimpta is used to treat adults with relapsing forms of multiple sclerosis (RMS).

How Kesimpta works
Kesimpta works by attaching to a target called CD20 on the surface of B cells. B cells are a type of white blood cell which are part of the immune system (the body's defences). In multiple sclerosis, the immune system attacks the protective layer around nerve cells. B cells are involved in this process. Kesimpta targets and removes the B cells and thereby reduces the chance of a relapse, relieves symptoms and slows down the progression of the disease.

2. What you need to know before you use Kesimpta

Do not use Kesimpta
- if you are allergic to ofatumumab or any of the other ingredients of this medicine (listed in section 6).
- 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 precautions
Talk to your doctor before using Kesimpta
- Kesimpta may cause the hepatitis B virus 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 hepatitis B virus, your doctor will ask you to see a specialist.
- Before you start treatment with Kesimpta, your doctor may check your immune system.
- If you have an infection, your doctor may decide that you cannot be given Kesimpta or may delay your treatment with Kesimpta until the infection is resolved.
- Your doctor will check if you need any vaccinations before you start your treatment with Kesimpta. 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 Kesimpta treatment. Other types of vaccines should be given at least 2 weeks before you start Kesimpta treatment.

While using Kesimpta
Tell your doctor:
- if you have a general injection-related reaction or a local injection-site reaction. These are the most common side effects of Kesimpta treatment and are described in section 4. They usually occur in the 24 hours after Kesimpta 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 Kesimpta 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 Kesimpta as this may result in infection. Other types of vaccines may work less well if they are given during treatment with Kesimpta.

Tell your doctor straight away if you get any of the following during your treatment with Kesimpta, because they could be signs of a serious condition:
- if you have rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, or feel faint. These could be signs or symptoms of an allergic reaction.
- if you think your multiple sclerosis is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms. These effects may indicate a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is caused by a virus infection.

Children and adolescents
Do not give this medicine to children and adolescents below 18 years of age because Kesimpta has not yet been studied in this age group.

Other medicines and Kesimpta
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 might take 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 (see “Warnings and Precautions” above).

Pregnancy and breast-feeding
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.

<u>Pregnancy</u>
You should avoid becoming pregnant while using Kesimpta and for 2 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 2 months after stopping Kesimpta. Ask your doctor about the available options.

If you do become pregnant or think you may be pregnant during treatment or within 2 months after the last dose, tell your doctor straight away. Your doctor will discuss with you the potential risks of Kesimpta on pregnancy. This is because Kesimpta can reduce the number of immune cells (B cells) in both the mother and the unborn baby. Your doctor should report your pregnancy to Novartis. You can also report your pregnancy by contacting the local representative of Novartis (see section 6), in addition to contacting your doctor.

Breast-feeding
Kesimpta can pass into breast milk in small amounts. Talk to your doctor about the benefits and risks before breast-feeding your baby while using Kesimpta.

Vaccination of newborn babies
Ask your doctor or pharmacist for advice before vaccinating your newborn baby if you have used Kesimpta during your pregnancy (see "Warnings and precautions" above).

Driving and using machines
Kesimpta is unlikely to affect your ability to drive and use machines.

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

3. How to use Kesimpta

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Kesimpta is given by subcutaneous injection (injection under your skin).

The first injection should take place under the guidance of a healthcare professional.

Kesimpta pre-filled pens are for single use only.

For detailed instructions on how to inject Kesimpta, see "Instructions for use of Kesimpta Sensoready Pen" at the end of this leaflet.

'QR code to be included' + www.kesimpta.eu

You can use Kesimpta at any time of day (morning, afternoon or evening).

How much Kesimpta to use and how often to use it

Do not exceed the dose prescribed by your doctor.

- The initial dosing is 20 mg Kesimpta 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 Kesimpta.

Time	Dose
Week 0 (first day of treatment)	20 mg
Week 1	20 mg
Week 2	20 mg
Week 3	No injection
Week 4	20 mg
Every month afterwards	20 mg

How long to use Kesimpta
Continue using Kesimpta every month for as long as your doctor tells you to.

Your doctor will regularly check your condition to determine whether the treatment is having the desired effect.

If you have questions about how long to use Kesimpta, talk to your doctor, pharmacist or nurse.

If you use more Kesimpta than you should
If you have injected too much Kesimpta, contact your doctor right away.

If you forget to use Kesimpta
To get the full benefit of Kesimpta, it is important that you have every injection on time.

If you have forgotten an injection of Kesimpta, 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 (see also "How much Kesimpta to use and how often to use it" above).

If you stop using Kesimpta
Do not stop using Kesimpta 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 Kesimpta 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.

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

4. Possible side effects

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

The side effects of Kesimpta are listed below. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse.

Very common (may affect more than 1 in 10 people)
- upper respiratory tract infections, with symptoms such as sore throat and runny nose
- injection-related reactions, such as fever, headache, muscle pain, chills and tiredness - these usually occur in the 24 hours after an injection of Kesimpta, in particular after the first injection
- urinary tract infections
- injection-site reactions, such as redness, pain, itching and swelling at the injection site

Common (may affect up to 1 in 10 people)
- decrease in the blood level of a protein called immunoglobulin M, which helps protect against infection
- oral herpes
- nausea, vomiting (have been reported in association with injection-related reactions)
- Increase in liver enzymes (shown in blood tests)

Not known (frequency cannot be estimated from the available data)
- allergic reactions, with symptoms such as rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, or feeling faint

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kesimpta

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

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Keep the pre-filled pen(s) in the outer carton in order to protect from light. Store in a refrigerator (2°C – 8°C). Do not freeze.
If necessary, Kesimpta can be left out of the refrigerator for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, Kesimpta can then be returned to the refrigerator for a maximum of 7 days.

Do not use this medicine if you notice that the solution contains visible particules or is cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kesimpta contains
- The active substance is ofatumumab. Each pre-filled pen contains 20 mg ofatumumab.
- The other ingredients are L-arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid (for pH adjustment) and water for injections.

What Kesimpta looks like and contents of the pack
Kesimpta solution for injection is clear to slightly opalescent, and colourless to slightly brownish-yellow.

Kesimpta is available in unit packs containing 1 pre-filled Sensoready Pen and in multipacks comprising 3 cartons, each containing 1 pre-filled Sensoready Pen.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Novartis Pharmaceuticals UK Limited.
2nd Floor, The WestWorks Building,
White City Place,
195 Wood Lane,
London,
W12 7FQ
United Kingdom

Manufacturer
Novartis Pharma GmbH
Roonstrasse 25
90429 Nuremberg
Germany 6

Novartis Farmacéutica SA
Ronda de Santa Maria 158
08210 Barbera del Vallès, Barcelona
Spain

Novartis Pharmaceuticals UK Limited.
2nd Floor, The WestWorks Building,
White City Place,
195 Wood Lane,
London,
W12 7FQ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Novartis Pharmaceuticals UK Limited
Tel: +44 1276 698370

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Instructions for use of Kesimpta Sensoready Pen

It is important that you understand and follow these instructions for use before injecting Kesimpta. Talk to your doctor, pharmacist or nurse if you have any questions before you use Kesimpta for the first time.

Remember:

- **Do not use** the pen if either the seal on the outer carton or the seal on the pen is broken. Keep the pen in the sealed outer carton until you are ready to use it.
- **Do not shake** the pen.
- If you drop your pen, **do not use** it if the pen looks damaged, or if you dropped it with the cap removed.
- Dispose of the used pen immediately after use. **Do not re-use a pen**. See "How should I dispose of the used Kesimpta Sensoready Pen?" at the end of these Instructions for Use.

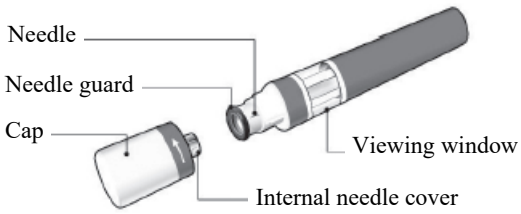
How should I store Kesimpta?

- Store the pen carton in a refrigerator between 2°C and 8°C.
- Keep the pen in the original carton until ready to use to protect from light.
- **Do not freeze** the pen.

Keep Kesimpta out of the sight and reach of children.

Kesimpta Sensoready Pen parts (see Picture A):

Picture A

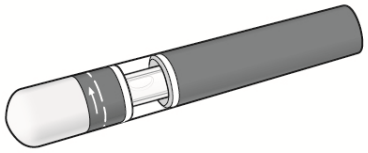


The Kesimpta Sensoready Pen is shown with the cap removed. **Do not** remove the cap until you are ready to inject.

What you need for your injection:
Included in the carton:

- A new Kesimpta Sensoready Pen (**see Picture B**)

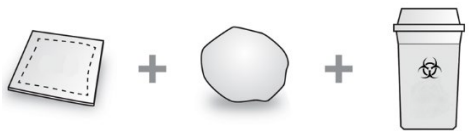
Picture B



Not included in the carton (**see Picture C**):

- 1 alcohol wipe
- 1 cotton ball or gauze
- Sharps disposal container

Picture C



See "How should I dispose of the used Kesimpta Sensoready Pen?" at the end of these Instructions for Use.

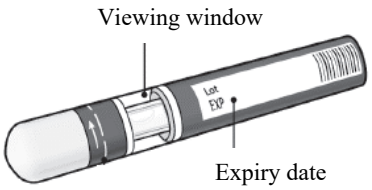
Before your injection:
Take the pen out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.

Step 1. Important safety checks before you inject (see Picture D):

- Look through the viewing window. The liquid should be clear to slightly opalescent.
  Do not use if the liquid contains visible particles or is cloudy.
  You may see a small air bubble, which is normal.
- Look at the **expiry date (EXP)** on your pen.
  Do not use your pen if the expiry date has passed.

Contact your pharmacist or healthcare professional if your pen fails any of these checks.

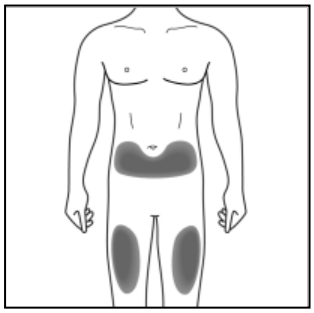
Picture D



Step 2. Choose your injection site:

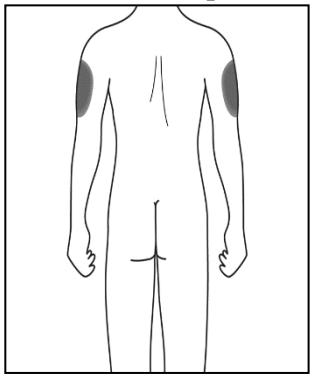
- The recommended site is the front of the thighs. You may also use the lower stomach area (lower abdomen), but **not** the area 5 cm around your navel (belly button) (**see Picture E**).
- Choose a different site each time you inject Kesimpta.
- **Do not inject** into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks or infection sites.

Picture E



- If a **caregiver** or **healthcare professional** is giving you your injection, they may also inject into your upper outer arm (**see Picture F**).

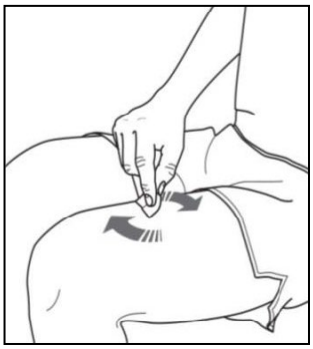
Picture F
(caregiver and healthcare professional only)



Step 3. Clean your injection site:

- Wash your hands with soap and water.
- Using a circular motion, clean the injection site with the alcohol wipe. Leave it to dry before injecting (**see Picture G**).
- Do not touch the cleaned area again before injecting.

Picture G



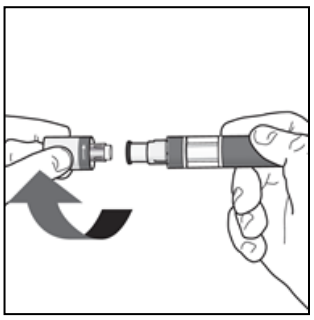
Your injection

Step 4. Remove the cap:

- Only remove the cap when you are ready to use the pen.
- Twist off the cap in the direction of the arrow (**see Picture H**).
- Throw away the cap. **Do not try to re-attach the cap.**
- Use the pen within 5 minutes of removing the cap.

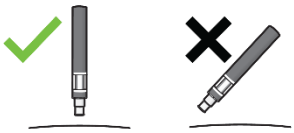
You may see a few drops of medicine come out of the needle. This is normal.

Picture H

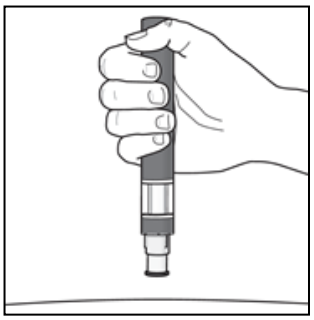


Step 5. Hold your pen:

- Hold the pen at 90 degrees to the cleaned injection site (**see Picture I**).



Picture I



Important: During the injection you will hear **2 loud clicks**:

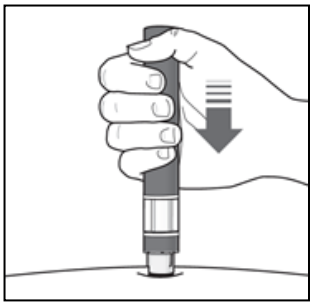
- The **first click** indicates that **the injection has started**.
- The **second click** indicates that **the injection is almost complete**.

You must keep holding the pen firmly against your skin until the **green indicator** fills the window and stops moving.

Step 6. Start your injection:

- Press the pen firmly against your skin to start the injection (**see Picture J**).
- The **first click** indicates that the injection has started.
- **Keep holding** the pen firmly against your skin.
- The **green indicator** shows the progress of the injection.

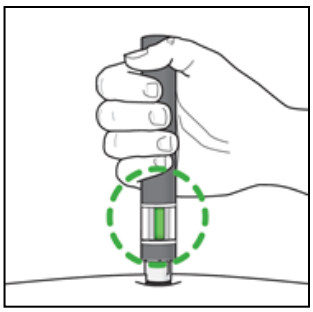
Picture J



Step 7. Complete your injection:

- Listen for the **second click**. This indicates that the injection is **almost** complete.
- Check if the **green indicator** fills the window and has stopped moving (**see Picture K**).
- You can now remove the pen (**see Picture L**).

Picture K



Picture L

After your injection:

- 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.
- There may be a small amount of blood at the injection site. You can press a cotton ball or 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 plaster, if the bleeding continues.

How should I dispose of the used Kesimpta Sensoready Pen?

Step 8. Dispose of your Kesimpta Sensoready Pen:

- Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar) (**see Picture M**).
- Never try to re-use your pen.

Keep the sharps container out of the reach of children.

Picture M