**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

# Kesimpta

**Solution for injection in pre-filled pen for subcutaneous injection**

**Active ingredient:**
Every 0.4 ml of pre-filled syringe contains 20 mg ofatumumab.
Every 1 ml Kesimpta is equivalent to 50 mg ofatumumab.

**Inactive ingredients and allergens:** See section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor of pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

## 1. What is this medicine intended for?

Kesimpta is intended for treating adults with relapsing forms of multiple sclerosis (RMS) who have an active disease as defined by clinical or imaging characteristics.

**Therapeutic group:** selective immunosuppressive medicines

How Kesimpta works
Kesimpta works by attaching to a receptor 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. Before using this medicine

**Do not use this medicine if:**

- you are sensitive (allergic) to ofatumumab or any of the other ingredients of this medicine (listed in section 6).
- you have been told that you have severe problems with your immune system.
- you are suffering from a severe infection.
- you have cancer.

**Special warnings about using this medicine**
**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 test 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. These side effects 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 symptoms during your treatment with Kesimpta, because they could be signs of a serious condition:
- 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**
This medicine is not intended for children and adolescents below 18 years of age.
There is no information about the safety and efficacy of using this medicine in children and adolescents below 18 years of age.

**Other medicines and Kesimpta**
**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**
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 medicines may have an added effect on the immune system.
- if you plan to have any vaccinations (see 'Special warnings about using this medicine', above).

**Pregnancy and breastfeeding**
If you are pregnant or breastfeeding, 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 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 Kesimpta. Ask your doctor about the available options.

If you do become pregnant or think you may be pregnant during treatment or within 6 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.

Breastfeeding
Kesimpta can pass into breast milk. Talk to your doctor about the benefits and risks before breastfeeding 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 'Special warnings about using this medicine' above).

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

**Important information about some of this medicine's ingredients**
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 according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Kesimpta is given by subcutaneous 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.
You can use Kesimpta at any time of day (morning, afternoon or evening).

**How much Kesimpta to use and how often to use it**
Only your doctor will determine your dose and how you should take this medicine.

**Do not exceed the dose recommended** by your doctor.

The recommended dosage is usually:
- 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.

**If you have accidentally taken a higher dose**
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.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting 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 process can take several months. During this time some side effects described in this leaflet may still occur.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**
**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

## 4. Side effects

Like with all medicines, using this medicine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

**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

**If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

## 5. How to store this medicine

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

**Storage conditions:** Keep the pre-filled pen in the outer carton in order to protect from light. Store in a refrigerator (2°C – 8°C). Do not freeze.
Do not use this medicine if you notice that the solution contains visible particles or is cloudy.

## 6. Additional information

In addition to the active ingredient, this medicine also contains:
arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid (for pH adjustment) and water for injections.

**What the medicine looks like and contents of the pack**

- Kesimpta solution for injection is clear to slightly opalescent, and colourless to slightly brownish-yellow.
- Each pack contains one pre-filled syringe for single use.

**Importer's name and address:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Approved in July 2021.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
167-85-36656-00

**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.

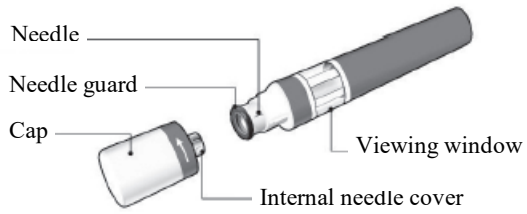
**How should I store Kesimpta?**

- 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**

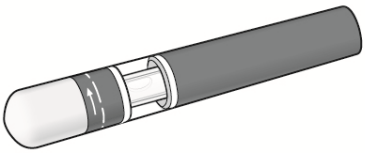



The Kesimpta Sensoready Pen is shown with the cap removed. **Do not remove** the cap until you are ready to inject.

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

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

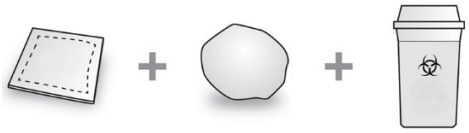
**Picture B**



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.

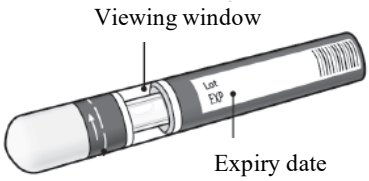
**Before your injection:**
Take the pen out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.

**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.

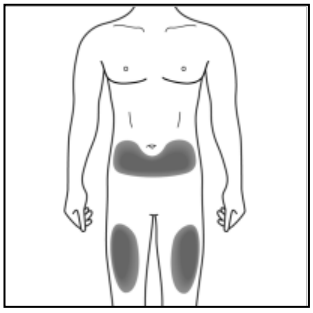
**Picture D**



**Step 2. Choose your injection site:**

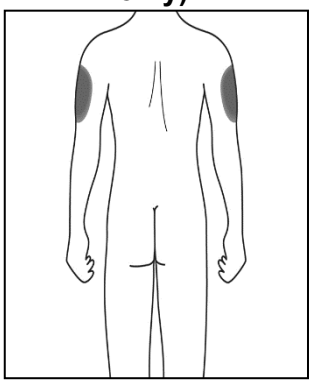
- The recommended site is the front of the thighs. You may also use the lower stomach area, but **not** the area 5 cm around your navel (belly button) (**see Picture E**).
- Choose a different site each time you inject Kesimpta.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly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

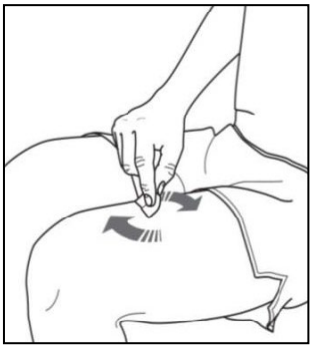
**Picture F**
**(caregiver and healthcare professional only)**



**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**

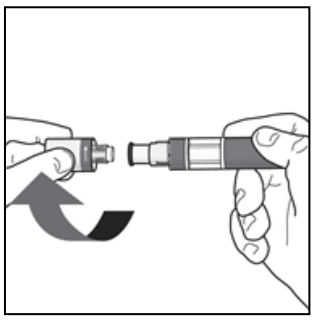


**Your injection**

**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.

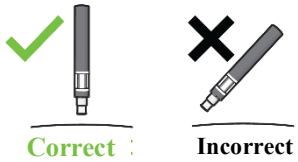
**Picture H**



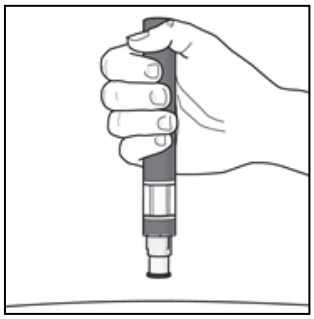
You may see a few drops of medicine come out of the needle.
This is normal.

**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:**

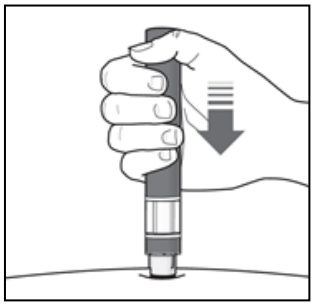
- **The first click** indicates that the **injection has started.**
- **The second click** indicates that the **injection is almost complete.**

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.

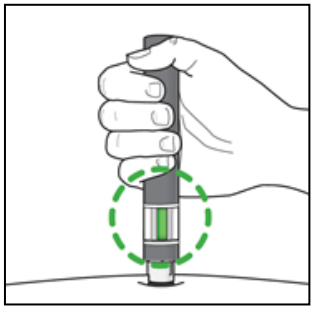
**Picture J**

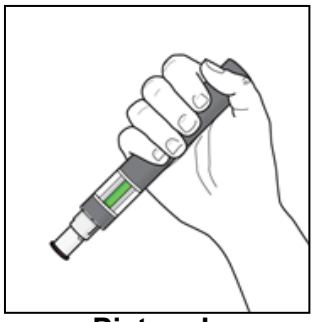


**Step 7. Complete your injection:**

- 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 reuse your pen.

**Picture M**

**Keep the sharps container out of the sight and reach of children.**