PATIENT PACKAGE INSERT 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:
ofatumumab 50 mg/ml

Each 1 ml of solution for injection contains 50 mg ofatumumab.
Each pre-filled pen contains 20 mg ofatumumab in 0.4 ml solution.

Inactive ingredients and allergens: See section 2 "Important information about some of the ingredients in this medicine" and section 6 "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

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

Therapeutic group: immunosuppressants, monoclonal antibodies

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 cells which are part of the immune system (the body's defenses). In multiple sclerosis, the immune system attacks the protective layer around the 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 THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to ofatumumab or any of the other ingredients in 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 regarding use of this medicine
Talk to the doctor before using Kesimpta
- Kesimpta may cause the hepatitis B virus to become active again. The 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, the doctor will ask you to see a specialist.
- Before starting treatment with Kesimpta, the doctor may check your immune system.
- If you suffer from an infection, the doctor may decide that you cannot be given Kesimpta or may delay your treatment with Kesimpta until the infection is resolved.
- The doctor will check if you need any vaccinations before starting 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 starting the treatment with Kesimpta. Other types of vaccines should be given at least 2 weeks before you start treatment with Kesimpta.

While using Kesimpta
Tell the doctor:
- if you have a general injection-related reaction or a local injection-site reaction. These are the most common side effects of Kesimpta 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 suffer from 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. The 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 the doctor immediately if you experience any of the following symptoms during your treatment with Kesimpta because they could be signs of a serious condition:
- if you have a 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 symptoms 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.

Drug Interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
In particular, inform the 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 additional effect on the immune system.
- if you plan to have any vaccinations (see "Special warnings regarding use of this medicine" above).

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to get pregnant, consult with a doctor before using this medicine.

Pregnancy
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 treatment with Kesimpta. Consult with a 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 immediately. The 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. You can report your pregnancy by contacting the local representative of Novartis (see section 6), in addition to contacting a doctor.

Breastfeeding
Kesimpta can pass into breast milk. Talk to the doctor about the benefits and risks before breastfeeding your baby while using Kesimpta.

Vaccination of newborn babies
Consult with a doctor or pharmacist before vaccinating your newborn baby if you have used Kesimpta during your pregnancy (see "Special warnings regarding the use of this medicine" above).

Driving and using machines
Kesimpta has no influence or has negligible influence on the ability to drive and use machines.

Important information about some of the ingredients in this medicine
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say, it is essentially "sodium-free".

3. HOW SHOULD YOU USE KESIMPTA?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
Kesimpta is given by subcutaneous injection (under the 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

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:
- Initial dosage of 20 mg Kesimpta administered on the first day of treatment (Week 0) and after one and two weeks (Week 1 and Week 2). After these first 3 injections, there is no injection the following week (Week 3).
- Starting at Week 4 and then once every month, the recommended dosage is 20 mg Kesimpta.

Time	Dosage
Week 0 (first day of treatment)	20 mg
Week 1	20 mg
Week 2	20 mg
Week 3	No injection
Week 4	20 mg
Once a month afterwards	20 mg

Do not exceed the recommended dose.

Treatment duration
Continue using Kesimpta once every month for the duration prescribed to you by the doctor.
The 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, refer to the doctor.

If you have accidentally taken a higher dosage
If you have injected too much Kesimpta, contact the doctor immediately.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

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).
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop using Kesimpta
Do not stop using Kesimpta or change your dosage without talking with the 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 a normal level. 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 each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Kesimpta may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The side effects of Kesimpta are listed below. If any of these side effects worsen, tell the doctor.

Very common – may affect more than 1 user in 10
- upper respiratory tract infections, with symptoms such as sore throat and runny nose
- injection-related reactions, such as fever, headaches, 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 1-10 in 100 users
- decrease in the blood level of a protein called immunoglobulin M, which helps protect against infections
- oral herpes
- nausea, vomiting (have been reported in association with injection-related reactions)

Side effects of unknown frequency (effects whose frequency has not been determined yet)
- 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

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health home page (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Side effects can also be reported to Novartis company via the email address: safetydesk.israel@novartis.com

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions
Keep the pen 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 particles or is cloudy.
Do not discard medicines in wastewater or in the household waste. Ask your pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

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

What the medicine looks like and the contents of the package
- Kesimpta is a clear to slightly opalescent, colorless to slightly brownish-yellow solution.
- Each package contains one pre-filled pen for single use.

Registration holder and Importer and its address: Novartis Israel Ltd., P.O.B. 7126, Tel Aviv.

Revised in July 2024.

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

Instructions for use of Kesimpta Sensoready Pen

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

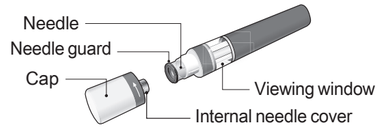
Remember:
- **Do not use** the pen if either the seal on the outer carton or the seal on the pen is broken. Keep the pen in the sealed outer carton until you are ready to use it.
- **Do not shake** the pen.
- If you drop your pen, **do not use it** if the pen looks damaged, or if you dropped it with 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.

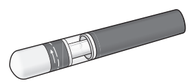
Kesimpta Sensoready Pen parts (see Picture A):

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 the injection: **Picture B**
Included in the carton:
- A new Kesimpta Sensoready Pen (**see Picture B**)

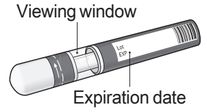


Not included in the carton (**see Picture C**): **Picture C**
- 1 alcohol wipe
- 1 cotton ball or gauze
- Sharps disposal container

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

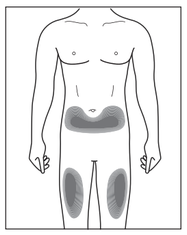
Before the injection:
Take the pen out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.

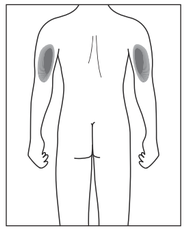
Step 1. Important safety checks before you inject (see Picture D): **Picture D**
- Look through the viewing window. The liquid should be clear to slightly opalescent. **Do not use** it if the liquid contains visible particles or is cloudy. You may see a small air bubble, which is normal.
- Look at the **expiry date (EXP)** on your pen. **Do not use** your pen if the expiry date has passed.



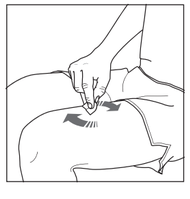
Contact the pharmacist or healthcare professional if your pen fails any of these checks.

Step 2. Choose the injection site: **Picture E**
- 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.
- 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)**

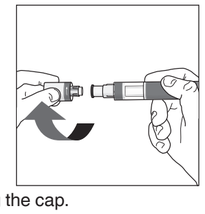




Step 3. Clean the injection site: **Picture G**
- Wash your hands with water and soap.
- Using a circular motion, clean the injection site with the alcohol wipe. Leave it to dry before injecting (**see Picture G**).
- Do not touch the cleaned area again before injecting.

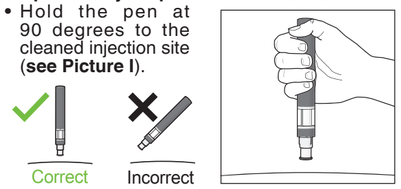


The injection
Step 4. Remove the cap: **Picture H**
- Only remove the cap when you are ready to use the pen.
- Twist off the cap in the direction of the arrow (**see Picture H**).
- Throw away the cap. **Do not try to re-attach the cap.**
- Use the pen within 5 minutes of removing the cap.



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

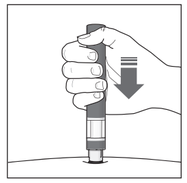
Step 5. Hold your pen: **Picture I**
- Hold the pen at 90 degrees to the cleaned injection site (**see Picture I**).



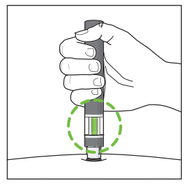
Important: During the injection you will hear **2 loud clicks**:
- **The first click** indicates that the **injection has started**.
- **The second click** indicates that the **injection is almost complete**.

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

Step 6. Start the injection: **Picture J**
- 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.



Step 7. Completion of the injection: **Picture K**
- 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 L

After the injection:
- If the green indicator does not fill the window, this means you have not received the full dose. Contact the 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 the Kesimpta Sensoready Pen: **Picture M**
- 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 sight and reach of children.

NOVARTIS

KES APL JUL24 V3