**PATIENT MEDICATION INFORMATION**

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrKESIMPTA®**

**ofatumumab injection**

**Pre-filled Sensoready® pen**

Read this carefully before you start taking **KESIMPTA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **KESIMPTA**.

**What is KESIMPTA used for?**

- KESIMPTA is used for the treatment of adults with relapsing remitting multiple sclerosis.
- It is not known whether KESIMPTA is safe and effective in children.

**How does KESIMPTA work?**

The active substance in KESIMPTA, ofatumumab is a type of protein called a monoclonal antibody designed to recognize and attach to a target called CD20 on the surface of certain types of white blood cells which are part of the immune system (so called B-cells).

Once an abnormal response by the body's immune system is triggered, these white blood cells play a role in multiple sclerosis by attacking the sheaths around the nerves in the brain and spinal cord, causing inflammation and damage. By targeting and removing the B-cells, KESIMPTA helps to reduce their activity and thereby reduces the chance of having a relapse, relieves symptoms and slows down the progression of the disease.

In controlled clinical studies in patients with relapsing forms of MS, KESIMPTA cut down significantly the number of attacks, significantly prolonged the time without relapses and slowed down the progression of the disease. The average number of relapses in patients treated with KESIMPTA was a little bit more than half in comparison to patients treated with another MS medicine teriflunomide.

If you have any questions about how KESIMPTA works or why this medicine has been prescribed for you, ask your healthcare professional.

**What are the ingredients in KESIMPTA?**

Medicinal ingredient: ofatumumab

Non-medicinal ingredients: L-arginine; sodium acetate trihydrate; sodium chloride; polysorbate 80; disodium edetate dihydrate; hydrochloric acid and water for injection.

**KESIMPTA comes in the following dosage forms:**

KESIMPTA is supplied as a 20 mg/0.4 mL pre-filled syringe* or a 20 mg/0.4 mL pre-filled Sensoready pen.

*Pre-filled syringes are not available in Canada.

**Do not use KESIMPTA if:**

- you are allergic to ofatumumab or any of the other ingredients in KESIMPTA (listed above) or component of the container
- you have active Hepatitis B virus (HBV) infection
- you have severe, active infections
- you have or have had confirmed progressive multifocal leukoencephalopathy (PML)
- you have been told that you have severe problems with your immune system
- you have cancer

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KESIMPTA. Talk about any health conditions or problems you may have, including if you:**

- **have an infection** before initiation of treatment with KESIMPTA, your healthcare professional may decide that you cannot receive KESIMPTA or may delay your treatment with KESIMPTA until the infection is resolved.
- **have a weakened immune system**. KESIMPTA taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

**After the initiation of treatment with KESIMPTA**

**Tell your healthcare professional during your treatment with KESIMPTA:**

- **if you have injection-related reactions or injection site reactions.** Injection-related reactions (general) and injection site reactions (local) are the most common side effects of KESIMPTA treatment. They generally occur after the first subcutaneous injection of KESIMPTA and up to 24 hours after the injection. The first subcutaneous injection should take place under the guidance of a healthcare professional.
- **if you have an infection.** Any infection that you already have may get worse. Infections could be serious and sometimes life-threatening.
- **if you have a lowered immune response** (due to a disease or medicines that suppress the immune system, see "Taking other medicines"). 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.
- **Tell your healthcare professional immediately,** if you get any of the following symptoms or diseases **during your treatment** with KESIMPTA, because there may be symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML):

  if you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms. These may also include weakness on one side of your body, loss of coordination in arms and legs, vision problems, changes in thinking and memory which may lead confusion and personality changes.

**Other warnings you should know about:**

**Before initiation of treatment with KESIMPTA**

- **Your healthcare professional will check if you are at risk of hepatitis B infection.** Before initiation of treatment with KESIMPTA, your healthcare professional will check if you are at risk of hepatitis B infection. All patients will have a blood test and patients who have had hepatitis B or are carriers of the hepatitis B virus will be referred to a specialized healthcare professional. KESIMPTA may cause the hepatitis B virus to become active again.
- **Your healthcare professional will check your immunoglobulin levels.** KESIMPTA may cause a decrease in some types of antibodies. Your healthcare professional will do blood tests to check your blood immunoglobulin levels.
- **If you plan to receive a vaccine,** tell your healthcare professional before initiation of treatment with KESIMPTA. You should receive your vaccines at least 4 weeks prior to starting KESIMPTA for live or live-attenuated vaccines and at least 2 weeks prior to starting KESIMPTA for the other vaccines. You should not receive certain types of vaccines (live or live-attenuated vaccines) during treatment with KESIMPTA. For the other vaccines, they can be less effective if administered during treatment with KESIMPTA.

**Children and adolescents (below 18 years)**

KESIMPTA has not been studied in patients below 18 years.

**Older people**

You can use KESIMPTA if you are aged 55 years or over at the same dose as younger adults.

**Pregnancy and breast-feeding**

**If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your healthcare professional for advice before using this medicine.**

Your healthcare professional will discuss with you the potential risks of using KESIMPTA during pregnancy. This is because KESIMPTA can reduce immune cells (B-cells) in the mother and unborn baby.

**Talk with your healthcare professional before breast-feeding while you use KESIMPTA.** KESIMPTA can pass into breast milk. Ask and discuss with your healthcare professional about the benefits and the risks of breast-feeding your baby while you use KESIMPTA.

**Talk with your healthcare professional before vaccinating your newborn.**

Ask your healthcare professional for advice before vaccinating your newborn, if you have used KESIMPTA during your pregnancy.

**Females of child-bearing potential**

**You should avoid becoming pregnant while using KESIMPTA and for 6 months after you stop using it.** KESIMPTA may harm your unborn baby. Female patients who might become pregnant

should use effective birth control methods during treatment and for 6 months after stopping KESIMPTA. Ask your healthcare professional about options of effective birth control.

**If you become pregnant or think you are pregnant,** tell your healthcare professional right away. You and your healthcare professional will decide what is best for you and your baby.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Before you use KESIMPTA, tell your healthcare professional if you are taking any of the following medicines:

- **Medicines that suppress or modulate the immune system including other medicines used to treat MS** such as ocrelizumab, cladribine, fingolimod, natalizumab, teriflunomide, mitoxantrone, or dimethyl fumarate due to a possible added effect on the immune system.
- **Vaccines.** If you need to receive a vaccine, seek your healthcare professional's advice first. During treatment with KESIMPTA, administration of some vaccines containing live virus (live-attenuated vaccines for example BCG for tuberculosis or vaccines against yellow fever) may result in infection.

**How to take KESIMPTA:**

- Always use this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Do not exceed the recommended dose prescribed by your healthcare professional.
- Your healthcare professional will give you or your caregiver training in the right way to prepare and inject. Do not try to inject KESIMPTA until you or your caregiver have been shown the right way by your healthcare professional.
- If recommended by your healthcare professional, before you take KESIMPTA, you may receive other medicines to prevent or reduce possible side effects of the injection.

**When to use KESIMPTA**

You can use KESIMPTA at any time (morning, afternoon, evening) for the scheduled dose.

**How to use KESIMPTA**

KESIMPTA is given by subcutaneous injection (injection under the skin). See Instruction for Use at the end of this leaflet for the details.

**How long to use KESIMPTA**

Continue using KESIMPTA every month for as long as your healthcare professional tells you.

This is a long-term treatment, possibly lasting for months or years. Your healthcare professional will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to use KESIMPTA, talk to your healthcare professional.

**If you stop using KESIMPTA**

Do not stop using KESIMPTA or change your dose without talking with your healthcare professional.

Some side effects can be related to having low level of B-cells in your blood. After you stop KESIMPTA your blood B-cells count will gradually increase to normal levels. 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 healthcare professional.

**Usual dose:**

- The initial dosing is 20 mg KESIMPTA administered by subcutaneous injection at weeks 0, 1 and 2. There is no injection at week 3.
- Starting at week 4 and then every month, the recommended dose is 20 mg KESIMPTA administered by subcutaneous injection.

**Dosage regimen with subcutaneous injection of KESIMPTA**

| Time | Dose |
|---|---|
| Week 0 (beginning of treatment) | 20 mg |
| Week 1 | 20 mg |
| Week 2 | 20 mg |
| Week 4 | 20 mg |
| Every month (starting from week 4) | 20 mg |

**Overdose:**

If you have used too much KESIMPTA at one time, or if you have used a first dose of KESIMPTA by mistake, contact your healthcare professional right away.

If you think you, or a person you are caring for, have taken too much KESIMPTA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If an injection of KESIMPTA is missed, it should be administered as soon as possible. Do not wait until the next scheduled dose. The treatment interval as recommended should be maintained for the following doses.

To get the full benefit of KESIMPTA, it is important that you receive each subcutaneous injection when it is due.

**What are possible side effects from using KESIMPTA?**

As with all medicines, patients treated with KESIMPTA may experience side effects, although not everybody gets them.

Side effects include the following listed below. If these side effects become severe, please tell your healthcare professional.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

**Very common:** *may affect more than 1 in 10 people*

- Upper respiratory tract infection with symptoms such as sore throat and runny nose
- Injection site reactions (local) such as redness, pain, itching and swelling at the injection site
- Injection-related reactions (general) such as fever, headache, muscle pain, chills and tiredness
- **Laboratory values (blood test results):** Decrease in specific proteins in the blood (immunoglobulins M ) which help protect against infection

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

- Keep out of reach and sight of children.
- Do not use this medicine after the expiry date, which is stated on the carton.
- Store between 2 to 8°C. Keep in the original package.
- Protect from light. 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.

Ask your healthcare professional how to dispose of medicines you no longer use.

**If you want more information about KESIMPTA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes

this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

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KESIMPTA and Sensoready are registered trademarks.

**Instruction for Use**

**Instructions for Use of KESIMPTA pre-filled Sensoready pen**

Be sure that you read, understand, and follow this "Instructions for Use" before injecting KESIMPTA. Talk to your healthcare professional if you have any questions before you use KESIMPTA Sensoready pen for the first time.

**Remember:**

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

Throw away (dispose of) the used KESIMPTA Sensoready pen right away after use. **Do not re-use a KESIMPTA Sensoready pen**. See "How should I dispose of used KESIMPTA Sensoready pen?" at the end of this "Instructions for Use".

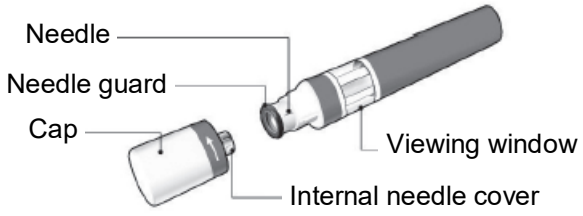
**How should I store KESIMPTA?**

- Store your carton of KESIMPTA Sensoready pen in a refrigerator, 2°C to 8°C.
- Keep KESIMPTA Sensoready pen in the original carton until ready to use to protect from light.
- **Do not freeze** KESIMPTA Sensoready pen.
- **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.

**Keep KESIMPTA and all medicines out of the reach of children.**

**KESIMPTA Sensoready pen parts (see Figure A):**

**Figure A**



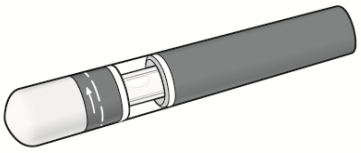

The KESIMPTA Sensoready pen is shown with the cap removed. **Do not** remove the cap until you are ready to inject.

**What you need for your injection:**

Included in the carton:

A new KESIMPTA Sensoready pen (**see Figure B**).

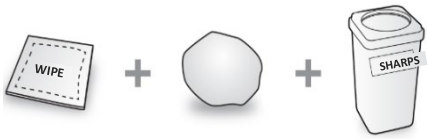
**Figure B**



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

**Figure C**

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



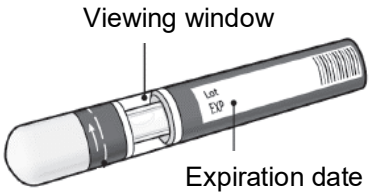

See "**How should I dispose of used KESIMPTA Sensoready pen?**" at the end of this "Instructions for Use"

**Before your injection:**

Take the KESIMPTA Sensoready 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 Figure D):**

**Figure D**



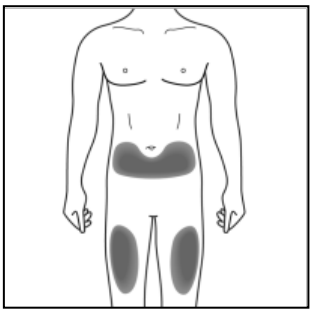

- Look through the viewing window. The liquid should be clear to slightly cloudy.
  **Do not use** if the liquid contains visible particles or is cloudy.

  You may see a small air bubble, which is normal.
- Look at the **expiration date (EXP)** on your KESIMPTA Sensoready pen. **Do not use** your Sensoready pen if the expiration date has passed.

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

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

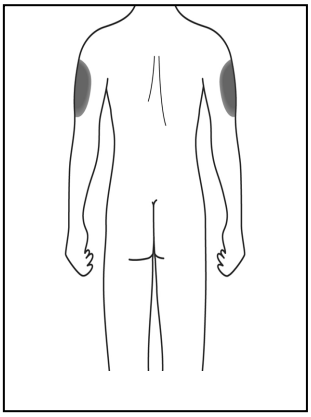
**Figure E**



- The recommended site is the front of the thighs. You may also use the lower stomach area (lower abdomen), but **not** the area five cm (2 inches) around the navel (belly button) (**see Figure 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.

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

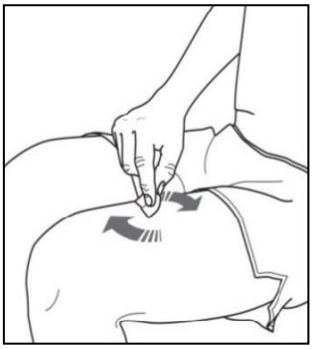
**Figure F**
**(Caregiver and healthcare professional only)**



**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 Figure G**).
- Do not touch the cleaned area again before injecting.

**Figure G**



**Your injection:**

**Step 4. Remove the cap:**

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

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

**Figure H**

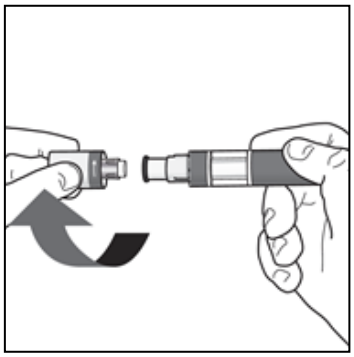
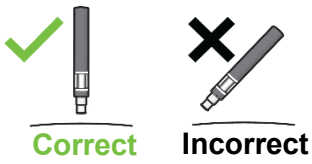
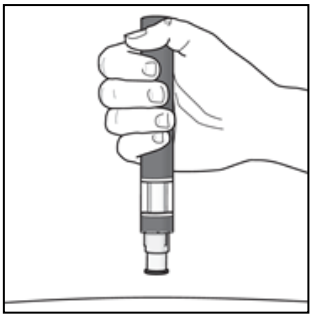


**Figure I**

**Step 5. Hold your KESIMPTA Sensoready pen:**

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



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

- The **1st click** indicates that **the injection has started**.
- A **2nd click** will indicate that **the injection is almost complete**.

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

**Figure J**

**Step 6. Start your injection:**

- Press the Sensoready pen firmly against the skin to start the injection (**see Figure J**).
- The **1st click** indicates the injection has started.
- **Keep holding** the Sensoready pen firmly against your skin.
- The **green indicator** shows the progress of the injection.

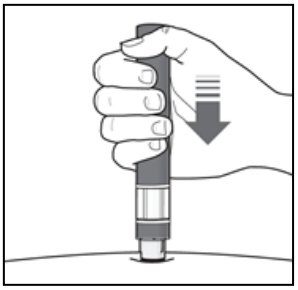
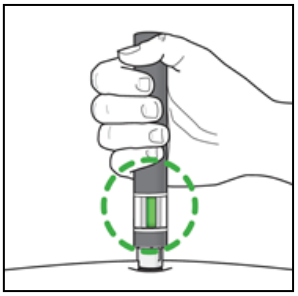


**Figure K**

**Step 7. Complete your injection:**

- Listen for the **2nd click**. This indicates that the injection is **almost** complete.
- Check to see if the **green indicator** fills the window and has stopped moving (**see Figure K**).
- The Sensoready pen can now be removed (**see Figure L**).

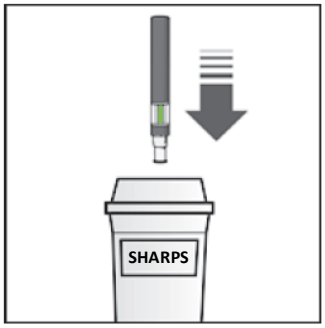


**After your injection:**

- In case the green indicator does not fill the window, it means the medicine has not been delivered. Contact your healthcare professional 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 bandage, if needed.

**Figure L**

**Figure M**




**How should I dispose of used KESIMPTA Sensoready pens?**

**Step 8. Dispose of your KESIMPTA Sensoready pen:**

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

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