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# **MSology Essentials Series**

# **KESIMPTA®**

(ofatumumab)

Developed by MSology with the invaluable assistance of multiple sclerosis nurse advisors:

#### **Bonnie Blain**

Central Alberta MS Clinic, Red Deer, Alberta

# **Peggy Cook**

MS Clinic, Saint John Regional Hospital, Saint John, New Brunswick

#### **Colleen Harris**

MS Clinic, University of Calgary, Calgary, Alberta

# **Shirley MacGowan**

Nurse educator, SK MS Drugs Program, Saskatoon, Saskatchewan

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# Why treat MS?

Multiple sclerosis (MS) is believed to be caused by an abnormal immune response, which results in inflammation and tissue damage in the brain and spinal cord (together called the central nervous system, or CNS). This inflammation is the cause of MS symptoms, such as nerve tingling, muscle weakness, vision problems, balance difficulties and pain. New or worsening MS symptoms that last for more than a day or two are called relapses, and these generally indicate an inflammatory flare-up in the CNS. Relapse symptoms can persist for several days, weeks or months. Some relapses will resolve completely and some will not. As you experience more and more relapses, the body is unable to repair the damage to the brain and spinal cord, which typically leads to physical and mental impairments.

That is why it is so important to treat MS – to reduce inflammation and tissue damage and reduce or delay disability. The medications prescribed are called disease-modifying therapies because they target the underlying MS disease process. They do not heal any tissue damage that has already occurred, but they may prevent further damage that will contribute to disability in the years ahead.

MS medications do not treat specific symptoms, so you will not feel an improvement in the symptoms you are having. The main effects of therapy are to lessen the frequency and severity of relapses and reduce the amount of new inflammation in the brain and spinal cord (seen as lesions on your magnetic resonance imaging [MRI] scan). So treatment can be seen as an investment in your future – lessening the damage that is occurring now to prevent disabilities later on.

# **How does Kesimpta work?**

Kesimpta is a medication that is injected under the skin (subcutaneous) to treat relapsing-remitting multiple sclerosis.

In MS, specialized cells of the immune system (called T and B cells) become activated, enter the CNS and cause inflammation and tissue damage. This inflammation can be reduced by eliminating B cells. Kesimpta is a human antibody that specifically targets these B cells to control MS disease activity. Clinical trials have shown that in people with MS, Kesimpta reduces the frequency of relapses, decreases the number of inflammatory lesions in the brain and delays the progression of physical disability.

Treatment with Kesimpta can be administered to people with relapsing-remitting MS if they have active disease, i.e. ongoing relapses or new lesions on their MRI. Talk to your neurologist about whether Kesimpta is the best option for treating your MS.

# How do I take Kesimpta?

#### **Dosing and administration**

For your privacy and convenience, Kesimpta was designed for you to self-administer in your own home. If you are concerned about self-injecting, you can ask a family member or friend to do the injections.

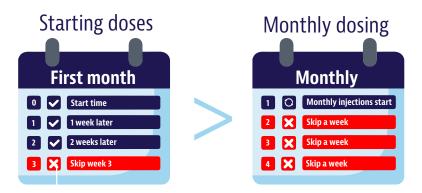
When you start your treatment course, you will need to administer 1 injection every week for 3 weeks in a row (weeks 0, 1 and 2). Take a break for 1 week (week 3). Then begin the regular injection schedule of 1 injection per month (starting week 4).

After the initial start-up period, the regular dosing schedule is 1 injection every month.

When starting treatment, try to schedule your first injection so that it falls on a date that is easy to remember, e.g. the 1st or 15th of the month.

You can take Kesimpta at any time of the day. Pick a time for your monthly dose that is most convenient to you (e.g. just before bedtime). If you later decide that you do not like this time, pick another time of day for your next injection.

If you forget to take a dose, simply take it whenever you remember. That new date will be the new schedule. E.g. you remember to take your May 1 dose on May 3. The next doses will be on June 3, July 3, etc.





Set up a reminder on your phone or calendar for when you should take your next injection.

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## How to inject Kesimpta

- Kesimpta is provided in a self-injector device called a Sensoready pen, which looks like a regular pen.
- After use, you will need to store the discarded pen in a sharps container (a hard plastic or metal container that can be sealed). Ask your pharmacist to provide one when you fill your prescription.
- Store Kesimpta in the refrigerator until you are ready to use it. Do not put it in the freezer. Keep out of reach of children.
- The best place to inject yourself is the front of the thigh. You can also inject the lower abdomen but not within 5 cm ( 2 inches ) of the navel ( belly button ).
- Try not to inject the same patch of skin twice. Choose a new part of the thigh or abdomen to inject every month.
- Do not inject an area of skin that is damaged (i.e. sores, moles, scars or stretch marks, piercings or tattoos).



Apply a cool cloth on your skin if the site of injection is red or sore. Talk to your MS clinic nurse for more tips on self-injecting.

# Step-by-step guide

Take 1 injection pen out of the refrigerator about 15-20 minutes before injecting so it will be at room temperature. You will also need an alcohol wipe and a cotton ball for the injection.





The whole process will only take a minute or two.

1	Wash your hands.
2	Clean the area you plan to inject with the alcohol wipe. Allow the area to dry before you inject.
3	Remove the cap from the Sensoready pen (no needle will be visible). You will need to inject yourself within 5 minutes after removing the cap. Do not shake the pen before using.
4	Position the pen at a 90-degree angle (straight up and down, not angled) over the area you plan to inject. PRESS down and HOLD the pen firmly against your skin. You will hear a CLICK.
5	While pressing and holding, watch the indicator window on the side of the pen – it will slowly turn GREEN. Keep pressing and holding until the indicator is completely green and you hear a second CLICK. This will take a few seconds.
6	Remove the pen once the injection is finished. Press (do not rub) a cotton ball on the injection site if you see a spot of blood.
7	Dispose of the pen in a sharps container. Keep the sharps container out of reach of children. When the container is full, talk to your Patient Support Program or pharmacist about the proper disposal of syringes so that they can be recycled.

# **Common questions**

#### How do I know my treatment is working?

During your course of treatment, your doctor will monitor your response to treatment with a variety of tests and procedures.

These typically include neurological examinations to evaluate your nerve and muscle function, and magnetic resonance imaging (MRI) to assess the extent of inflammatory activity in your brain and spinal cord. Periodic blood tests may be required for safety reasons. Other tests and procedures may also be needed during your course of treatment.

#### What if I have a relapse?

A relapse is a new MS symptom you haven't had before, or a worsening of symptoms you've previously experienced. The symptom persists for at least 24 hours. If you become overheated – from exercise, a hot bath, a fever or infection – your MS can worsen for a short period of time, but these symptoms are not a true relapse.

It is important to inform your neurologist or MS nurse if you experience a relapse or any new or worsening symptoms that last more than 24 hours. A relapse can occur soon after starting treatment with Kesimpta, especially if your MS was very active before, but this generally means that the medication has not had time to be fully effective.



Ongoing treatment is needed to control MS so be sure to keep to the schedule of monthly injections – even if your injection is due during a vacation or business trip. You may experience a relapse or worsening MS if you skip a dose.

## What are the possible side effects of this medication?

# Injection reactions

- Some people will have redness, pain, itching or swelling where they
  have injected themselves. Symptoms are typically mild or moderate
  in severity and are not serious.
- After the injection, you may experience a slight fever, headache, muscle aches, chills or fatigue. These symptoms usually become less common as your body gets used to the medication.

#### Infections

- Treatment is associated with an increased risk of upper respiratory tract infections, such as colds or influenza. If you develop a severe or persistent infection, contact your family doctor or MS clinic nurse.
- Some people may develop a urinary tract infection (UTI) during treatment. Contact your family doctor and MS clinic nurse if you develop UTI symptoms, such as a change in bladder habits (e.g. more frequent or urgent urination), pain or burning sensation when urinating, or blood in the urine.
- · Note: more potent medications such as Kesimpta may be associated with a higher risk of PML (progressive multifocal
- · leukoencephalopathy), a serious brain infection. No cases of PML have been reported in MS patients taking Kesimpta.



If your injections are giving you headaches or aches and pains, ask your MS clinic nurse about whether you should take a non-prescription pain reliever before or after injecting. Report any new, unusual or worrisome symptoms during treatment to your family doctor, neurologist or MS nurse.

# **Tests and procedures**

During your course of treatment, your doctor will order a number of tests to ensure that your medication is working and not causing any unwanted effects. Procedures may vary at different clinics. Your neurologist and MS nurse will schedule which tests you will need and how often they should be done.



Test/procedure*	Reason	How often	
Hepatitis B screening	· To make sure you do not have hepatitis.	Before starting Kesimpta	
Vaccination status	<ul> <li>To confirm that you are up-to-date with your regular vaccinations (e.g. measles, mumps, diphtheria, tetanus)</li> </ul>	Before starting Kesimpta	
Blood test	<ul> <li>To check antibody levels</li> <li>To check liver and kidney function</li> <li>To confirm that you do not have hepatitis</li> </ul>	Before starting Kesimpta and periodically during treatment	
Pregnancy test	· To ensure you are not pregnant	Before starting Kesimpta or if pregnancy is suspected	
Injection training	To demonstrate how to self-in- ject correctly	Before starting Kesimpta (instruction provided by your patient support program)	
Magnetic resonance imaging (MRI)	To evaluate your response to treatment	Periodically during treatment	

<sup>\*</sup>The frequency of tests will vary depending on your MS clinic. Your neurologist or MS nurse will tell you more about the specific tests and when you'll need them during treatment. Please ensure that you DO all of the necessary tests at the recommended times.

# **Pregnancy**

You should not take Kesimpta if you are pregnant. Women of childbearing age should use effective contraception during treatment and for at least 6 months after stopping the medication.



If you are planning a pregnancy, it is best that your MS is well-controlled (no relapses or new MRI lesions) for a year before trying to get pregnant. Once your MS flare-ups have been managed, you and your neurologist can discuss interrupting your treatment so you can start trying to get pregnant.

If you become pregnant during treatment, stop taking Kesimpta and notify your neurologist immediately.

# **Breastfeeding**

It is generally advisable to be drug-free during breastfeeding. So you will need to weigh the benefits of breastfeeding compared to the benefits of restarting treatment after childbirth to control your MS. Your neurologist or MS clinic nurse can advise you about the optimal timing of breastfeeding and when to resume your medication according to your unique circumstances and personal preferences.



#### Other medications

All medications have the potential to interact with other drugs you are taking. This includes other prescription medications, as well as non-prescription drugs and alternative/complementary therapies.



There are no known drug interactions with Kesimpta. For safety reasons, you should not take Kesimpta with other disease-modifying therapies used to treat MS, or immune-suppressing drugs commonly used to treat cancer.

Talk to a healthcare professional before taking any new medication. Your doctor, MS nurse or pharmacist can advise you about any interactions that may occur.

There are no known interactions between Kesimpta and food so you can eat just before or after your injection.

#### Other medical conditions

Always ensure that your doctor is aware of any other medical conditions you may have. This includes high blood pressure, liver or kidney problems, diabetes, infections, or other illnesses.

Kesimpta cannot be taken by people with an active hepatitis B infection. Hepatitis B is a virus that is transmitted via blood or bodily fluids (not by sneezing or coughing). Symptoms of active infection can include abdominal pain, dark urine, loss of appetite or jaundice ( yellowing of the skin or the whites of the eyes ). Talk to your doctor if you suspect that you have active hepatitis.

If you develop an infection (e.g. urinary tract infection, bronchitis), be sure to see your family doctor to have it treated. While it is important to keep to the monthly schedule of Kesimpta, in some situations it may be best to delay Kesimpta for a few days until your infection has cleared up. You will need to inform your neurologist and MS clinic nurse if you are getting frequent infections and if you have delayed or skipped any doses of Kesimpta.

## **Resources in your community**

Your neurologist or MS nurse can provide you with information on the Novartis Go program, which offers information and support for people taking Kesimpta. The program can assist you with your injections and provide you with information about your MS.





Injectable drugs can raise questions with border officials when you travel to other countries. Your MS clinic can provide you with a doctor's letter explaining that you are authorized to take Kesimpta.

Notes		

## **MS Essentials Series**

The MS Essentials series provides the latest information on multiple sclerosis medications, research, and lifestyle issues such as health, nutrition and exercise. All of the booklets are developed by Lind Publishing, publishers of MSology, to help people affected by MS remain active and informed. MS Essentials ressources are provided free of charge. The full series of publications is available for download on http://www.MSology.com.

The information reflects use of the medication in Canada; use may vary in other countries. MSology does not approve, endorse or recommend any specific product or therapy. Contact your healthcare providers before you start treatment, alter the dose, interrupt or discontinue your therapy. For full information about a specific medication, consult the prescribing information or package insert provided by the manufacturer for your country.



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For more multiple sclerosis information, visit www.MSology.com

