MEDICATION GUIDE

KESIMPTA® (KEY-simp-ta)

(ofatumumab)

injection, for subcutaneous use

What is the most important information I should know about KESIMPTA?

KESIMPTA can cause serious side effects, including:

Infections. Serious infections, which can be life-threatening or cause death, can happen during treatment with KESIMPTA. If you have an active infection, your healthcare provider should delay your treatment with KESIMPTA until your infection is gone. KESIMPTA taken before or after other medicines that weaken the immune system may increase your risk of getting infections.

Tell your healthcare provider right away if you have any infections or get any symptoms, including painful and frequent urination, nasal congestion, runny nose, sore throat, fever, chills, cough, or body aches.

- **Hepatitis B virus (HBV) reactivation.** Before starting treatment with KESIMPTA, your healthcare provider will do blood tests to check for HBV. If you have ever had HBV infection, the HBV may become active again during or after treatment with KESIMPTA. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems, including liver failure or death. You should not receive KESIMPTA if you have active hepatitis B liver disease. Your healthcare provider will monitor you for HBV infection during and after you stop using KESIMPTA.

Tell your healthcare provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes during treatment with KESIMPTA.

- **Progressive Multifocal Leukoencephalopathy (PML)**. PML may happen with KESIMPTA. PML is a rare, serious brain infection caused by a virus that may get worse over days or weeks. PML can result in death or severe disability. Tell your healthcare provider right away if you have any new or worsening neurologic signs or symptoms. These may 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 to confusion and personality changes.
- **Weakened immune system**. KESIMPTA taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

What is KESIMPTA?

KESIMPTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS), including:

- clinically isolated syndrome
- relapsing-remitting disease
- active secondary progressive disease

It is not known if KESIMPTA is safe or effective in children.

Do not use KESIMPTA if you:

- have an active hepatitis B virus infection.
- have had an allergic reaction to ofatumumab or life-threatening injection-related reaction to KESIMPTA. See the end of this Medication Guide for a complete list of ingredients in KESIMPTA.

Before using KESIMPTA, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection, including HBV or PML. See **"What is the most important information I should know about KESIMPTA?"**
- have ever taken, currently take, or plan to take medicines that affect your immune system. These medicines could increase your risk of getting an infection.
- have a history of liver problems.
- have had a recent vaccination or are scheduled to receive any vaccinations.
    - **You should receive any required 'live' or 'live-attenuated' vaccines at least 4 weeks before you start treatment with KESIMPTA**. You **should not receive** 'live' or 'live-attenuated' vaccines while you are being treated with KESIMPTA and until your healthcare provider tells you that your immune system is no longer weakened.
    - **Whenever possible, you should receive any 'non-live' vaccines at least 2 weeks before you start treatment with KESIMPTA**.

- Talk to your healthcare provider about vaccinations for your baby if you used KESIMPTA during your pregnancy.

- are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if KESIMPTA will harm your unborn baby. Females who can become pregnant should use birth control (contraception) during treatment with KESIMPTA and for 6 months after your last treatment. Talk with your healthcare provider about what birth control method is right for you during this time.
    - **Pregnancy Registry:** There is a registry for women who become pregnant during treatment with KESIMPTA. If you become pregnant while taking KESIMPTA, tell your healthcare provider right away. Talk to your healthcare provider about registering with the MotherToBaby Pregnancy Study in Multiple Sclerosis. The purpose of the registry is to collect information about your health and your baby's health. For more information or to register, contact MotherToBaby by calling 1-877-311-8972, by sending an email to MotherToBaby@health.ucsd.edu, or go to www.mothertobaby.org/join-study.
- are breastfeeding or plan to breastfeed. It is not known if KESIMPTA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take KESIMPTA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use KESIMPTA?

See the detailed Instructions for Use that comes with KESIMPTA for information about how to prepare and inject a dose of KESIMPTA and how to properly throw away (dispose of) used KESIMPTA Sensoready pens or prefilled syringes.

- Use KESIMPTA exactly as your healthcare provider tells you to use it.
- KESIMPTA is given as an injection under your skin (subcutaneous injection), in your thigh or stomach-area (abdomen) by you or a caregiver. A caregiver may also give you an injection of KESIMPTA in your upper outer arm.
- Your healthcare provider will show you how to prepare and inject KESIMPTA the right way before you use it for the first time.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with moles, scars or stretch marks.
- The initial dosing is 20 mg of KESIMPTA given 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 of KESIMPTA administered by subcutaneous injection.
- If you miss an injection of KESIMPTA at Week 0, 1, or 2, talk to your healthcare provider. If you miss a monthly injection, give it as soon as possible without waiting until the next scheduled dose. After that, give your KESIMPTA injections a month apart.

What are the possible side effects of KESIMPTA?

KESIMPTA may cause serious side effects, including:

See **"What is the most important information I should know about KESIMPTA?"**

- **Injection-related reactions.** Injection-related reactions are a common side effect of KESIMPTA. Injecting KESIMPTA can cause injection-related reactions that can happen within 24 hours (1 day) following the first injection and with later injections. There are two kinds of reactions:
    - **at or near the injection site**: redness of the skin, swelling, itching and pain. Talk with your healthcare provider if you have any of these signs and symptoms.
    - **that may happen when certain substances are released in your body**: fever, headache, pain in the muscles, chills, tiredness, rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue and throat, and feeling faint, or chest tightness. Contact your healthcare provider right away if you experience any of these signs and symptoms, especially if they become worse or you have new severe signs of reactions after subsequent injections. It could be a sign of an allergic reaction, which can be serious.
- **Low immunoglobulins**. KESIMPTA may cause a decrease in some types of antibodies. Your healthcare provider will do blood tests to check your blood immunoglobulin levels.

- **Liver damage**. KESIMPTA may cause liver damage. Your healthcare provider will do blood tests to check your liver before you start KESIMPTA and while you take KESIMPTA if needed. Tell your healthcare provider right away if you have any symptoms of liver damage, such as:
    - yellowing of the skin and eyes (jaundice)
    - nausea
    - vomiting
    - unusual darkening of the urine
    - feeling tired or weak

The most common side effects of KESIMPTA include:

- upper respiratory tract infection, with symptoms, such as sore throat and runny nose, and headache. See "**What is the most important information I should know about KESIMPTA?"**
- headache

These are not all the possible side effects of KESIMPTA. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How should I store KESIMPTA?

- Store KESIMPTA in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep KESIMPTA in the original carton until ready for use to protect from light.
- If needed, KESIMPTA may be stored for up to 7 days at room temperature, up to 86°F (30°C).
- Write the date taken out of the refrigerator in the space provided on the carton.
- If stored below 86°F (30°C), unused KESIMPTA may be returned to the refrigerator and must be used within the next 7 days. If this KESIMPTA is not used within those 7 days, then discard the medicine.
- Do not freeze KESIMPTA.
- Do not shake KESIMPTA.

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

General information about the safe and effective use of KESIMPTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KESIMPTA for a condition for which it was not prescribed. Do not give KESIMPTA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about KESIMPTA that is written for health professionals.

What are the ingredients in KESIMPTA?

Active ingredient: ofatumumab

Inactive ingredients: Sensoready Pen and prefilled syringe: arginine, disodium edetate, polysorbate 80, sodium acetate trihydrate, sodium chloride, and Water for Injection. Hydrochloric acid may be added.

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936

For more information, go to www.novartis.us or call 1-888-669-6682.

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