# THROUGH OUR LENS

**SUMMER 2024** 

## MULTIPLE SCLEROSIS

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Meeting the challenge



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"Most MS studies have very low representation of Black and other [minority] populations."

- Mitzi Joi Williams, MD, medical director of Joi Life Wellness Group MS Center in Atlanta







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### **Multiple Sclerosis**



### MS BRAIN FOG

Up to 60% of people with MS have problems with memory or thinking clearly. Black people might be among those at greatest risk. A very small group of White, Black, and Hispanic people with MS took a test that doctors often use to detect the earliest signs of cognitive decline. Though everyone in the study was similar in age, physical abilities, and how long they'd had MS, Black and Hispanic people scored significantly lower on the thinking skills test. More research is needed to confirm this connection, and it takes more testing to diagnose a real problem.

SOURCE: Multiple Sclerosis and Related Disorders

## DOES RACE PLAY A ROLE IN TREATMENT OPTIONS?

A recent study finds that MRIs of Black people with MS are worse than those of White people. The images tend to reveal more damage and scarring in the central nervous system and more loss of brain volume. It's likely a combination of factors that makes MS more severe for some Black people. Among those factors, the study shows, is that Black people respond to treatments differently. For example, drugs called anti-CD20s might be better for Black people than beta interferons. Ask your doctor whether your race might play a part in treatment choice.

3 in 1,000
Estimated number of Black Americans who have MS.
SOURCE: JAMA Neurology

16

Average number of years with MS before a Black person needs to use a cane.

SOURCE: Neurology

## BE A PART OF THE SOLUTION

For a long time, experts believed that Black people didn't get MS. Though that's been proven wrong, Black people are still grossly underrepresented in research about MS. That makes it hard to learn how the disease and treatments might affect people of color differently. A new initiative aims to change that. A team of doctors and scientists launched the National African Americans with MS



Registry. Black people who have MS can join the registry and learn about opportunities to participate in research and advance understanding of the unique ways MS affects them.

SOURCES: National Multiple Sclerosis Society and National African Americans with MS Registry

SOURCE: Frontiers in Neurology



For more on treatment, read Peer to Peer: **Choosing Multiple** Sclerosis Treatment. Use your smartphone camera to activate the QR code.

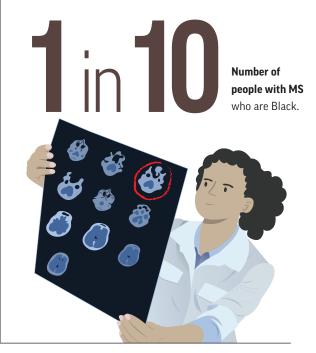
## STATS & FACTS

By Sonya Collins Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs



Number of people that need to switch to more powerful MS drugs who are Black.

## Number of people that switch medications due to bad side effects who are Black.

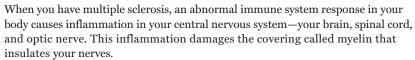


# MS IN BLACK PEOPLE

### How the disease impacts our community

By Rachel Reiff Ellis

Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs



When myelin is damaged, the flow of information in your brain and from your brain to the rest of your body gets interrupted. This causes symptoms such as numbness, trouble walking, vision issues, fatigue, and changes in thinking ability.

Until recently, the medical community considered multiple sclerosis a rare disease in the Black community. In reality, about 3 out of every 1,000 Black Americans lives with MS, compared to 4 out of every 1,000 White Americans.

"The idea of its rarity [in the Black community] has been debunked," says Dorlan J. Kimbrough, MD, a neurologist at Duke Neurological Disorders Clinic and assistant professor of neurology at Duke University School of Medicine in Durham, NC. "Epidemiological studies during the past several years have revealed that the incidence of MS in Black people is typical of expected rates in the U.S., if not disproportionately higher in some regions."

#### **MISSED DIAGNOSES**

Research shows that when it comes to total numbers, MS is highest in the White community. But when it comes to incidence (number of new cases), the picture looks different: A study of women showed that the number of new cases is higher in Black women than in White women.

"MS used to be known as a young White woman's disease," says Annette Howard, MD, medical director of the Multiple Sclerosis Institute of Texas in Houston and member of the MSAA African American Advisory Board.

Because of this, she says, doctors have often overlooked MS as a diagnosis in Black adults, even when they have symptoms of the disease.



"When other races would present with symptoms of MS, doctors would disqualify them because the patients were not young and White," she says. "They may come in and have the same symptoms of MS and think it's

#### SO YOU HAVE MS

Annette Howard, MD, recommends first steps after an MS diagnosis.

- ★ Partner with an MS specialist. One who listens and meets your needs.
- Reach out. Take part in support communities.
- ★ Share your status. Tell friends and family about your MS so they know your needs.



a stroke just because they're Black, or because they have high blood pressure or diabetes and then miss a diagnosis of MS because they'll focus on that. You even have patients who report that doctors say, 'If I didn't know any better, I'd think you had MS,' and then that's exactly what they have."

#### REPRESENTATION IN RESEARCH

MS may affect Black people differently than it does White people, too, with faster progression and more complications. This may be because of delayed treatment.

"In some cases, Black patients may have been diagnosed or treated later in the disease course, leading to greater disability before the start of treatment," Kimbrough says.

But minority populations are also underrepresented in clinical trials in the U.S. Black patients made up only 0.5% to 5.3% of all participants in four clinical trials from 2017 to 2020 that led to FDA-approval for certain MS drugs.

Because this limits the data available on MS in Black adults, it's harder for doctors to make informed decisions about how treatments will work in their Black patients. Also lacking is the information on how the environment for Black populations may affect their risk of MS and outcomes with the disease.

"There is ongoing research to evaluate the impact of social determinants of health on the long-term course of MS progression," Kimbrough says.

#### **GETTING ACCURATE NUMBERS**

Researchers are working to better understand what kind of impact MS has in the Black community, and that includes an accurate record of those living with the disease.

"In 2020, three other colleagues and I started an African American MS registry," Howard says. "Our objective is to capture through demographic information the estimated 30,000 African Americans who have a diagnosis of MS in the United States."

Through the registry, Howard says, patients receive a survey to get their demographic information. In return, the registry provides newsletters about MS issues, including emerging treatments and clinical trial information.

#### WHAT CAUSES MS?

Doctors haven't found a single cause of the disease, but several factors play a part.

- Genes
- Your sex
- Viral infections
- Vitamin D levels
- **Environment**

## Here's why I'm taking an active role in my health

By Brianna Pearson Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

Multiple sclerosis (MS) came as a very unwelcome 1-year anniversary gift. I had moved to Chicago from Detroit, was newly married, and had just had my "honeymoon" baby. It was the middle of the [COVID-19] pandemic, and I, like so many others, was trying to navigate this new normal. Then, my life changed drastically.

#### **MY DIAGNOSIS**

The day of my first wedding anniversary, I woke up with what looked like a stripe in front of my eye. My vision was very cloudy. I didn't want to miss dinner with my husband and the celebration, so I promised to go to the urgent eye center the next day. I really blew it off and thought that maybe my toddler had headbutted me in the eye during my sleep. The eye doctor said that it looked like optic neuritis and that I should go to the doctor immediately as that is often a sign of MS. My mind was swirling. At this time, COVID was surging again and I had a long wait in







with a list of side effects and risks. Some options were ruled out due to my medical history. It was all so overwhelming.

#### A STABLE PLACE

A lot has happened in the past 2 years. In addition to getting a diagnosis that has changed my life, I've seen my true strength. I've been diligent about researching my treatments, getting second opinions, and being honest with my doctors about my questions or concerns. I still have bad days, but I've taken an active role in my health—I changed my diet, I try to move a little more, and I see a therapist for my mental health. I've joined a support group for other women of color with MS and attended a wellness retreat. It was life-changing to walk into a room to see women who look like me who are all battling MS. I've become more confident in telling my story hopefully to help others.

the emergency room to get an MRI. My spinal tap was done in a storage closet because the hospital was full.

After getting my results, the doctor came in and said the words: multiple sclerosis. He confirmed lesions were on my brain and spine. I was in shock, and he basically sent me on my way.

#### THINGS MOVE FAST

I wanted to get an appointment with an MS specialist right away, but unfortunately, there was a wait. I had another relapse, and by the time I got an appointment, I had lost vision in my left eye. My diagnosis journey was fast-tracked compared to so many people. Although I was pointed in the right direction, the process of

getting treatment and recovery was tough. I left that hospital feeling unheard, undertreated, and dismissed. I ended up relapsing a month later while I was in the process of waiting for a referral.

It wasn't until I took matters into my own hands and found a new hospital system that I got the help I needed. My MS doctor (who was so helpful) put me on a course of steroids right away and then monthly infusions. My symptoms began to fade, but my depression was only getting worse. Here I was a new wife, with a new baby, a blended family with three other children, and living in a new city. It was a lot! I felt like I was spiraling. I had so many decisions to make-each treatment came



# KNOWLEDGE IS POWER

### Why staying informed makes it easier to make decisions

By Rachel Reiff Ellis Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs



As you take on life with multiple sclerosis, you're entering a world with what seems like a whole new language. Terms like "relapse" and "lesion" and acronyms like "MRI" and "DMT" are now part of your vocabulary.

The learning curve may feel steep. But the climb is not only worth it, it's a path to optimal MS care. When you're proactive in learning more about your disease, you become empowered to take part in your treatment choices.

#### **PARTNERS IN CARE**

"We call it shared decision making," says Sandra Parawira, nurse practitioner at the Waddell Center for Multiple Sclerosis at UC Health in Cincinnati, OH. "It's a model of care that encourages partnership and collaboration between you and your provider."

This model of care works best, says Parawira, when both sides are engaged in the process. For example, instead of simply showing up to your appointments, come with a list of your goals, questions, and concerns ready.

"When you're curious about your disease and work on learning more, you benefit," Parawira says. "Educated patients are often better able to make informed decisions about how they want to live their lives and what they want to do in terms of trying to be as healthy as possible in the face of a chronic progressive disease like MS."

#### WHERE TO GET YOUR INFORMATION

Your neurologist will likely be your primary source of guidance, especially when it comes to choosing the MS treatment that works best for you. But they don't need to be—and shouldn't be—your sole source for information.

"Most clinics use a comprehensive team approach to care, which means you have access not only to a neurologist, but also to nurse practitioners, physician assistants, and other advanced care providers," Parawira says.

Often, she says, these other advanced care providers may have more time to spend to delve into specific issues you have, especially about symptom management. Utilize all the resources available to you so you can get all your questions answered.

In between face time with professionals, research what you can and keep a list of questions that pop up as you do. Bring them in to your next appointment and talk them through with your care team.

"You want to increase what's called your 'health literacy," Parawira says. "That's your ability to find, understand, and use information and services to make health-related decisions."

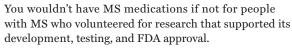
Her advice: Ask your MS team for advice on reliable sites and organizations to investigate. Or if you come across information on your own, check that it's sound and medically based.

"Our understanding of MS is changing all the time," Parawira says. "Keep asking questions and keep learning. That knowledge is one of the best tools you have for empowering yourself."

# **IMPROVE** YOUR CARE

You and your family can help advance researchers' understanding of MS in Black people

By Sonya Collins Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs



You, and maybe your family, can participate in MS research, too. It could improve your care and help advance understanding of how MS and its treatments affect Black people.

Consider this: Until fairly recently, doctors thought that Black people probably didn't get MS. It was research, and the Black people who participated in it, that corrected that longstanding myth.

"Most MS studies have very low representation of Black and other [minority] populations," says Mitzi Joi Williams, MD, medical director of Joi Life Wellness Group MS Center in Atlanta. "If we want treatments to reflect our community, we have to stand up and be counted."

#### WHAT YOU CAN DO

Clinical trials test how well a new treatment works on a large group of people with a certain disease. This research is critical to treating any disease, but it's not the only way you can help advance MS research.

You could donate blood, saliva, or tissue to MS research. You can answer surveys that include questions about your background, your disease symptoms and severity, and



your lifestyle. Some surveys involve family members, too. You could join a diet or exercise program to help researchers see if it benefits people with MS.

"There are a ton of ways to get into research even if you're not interested in clinical trials," Williams says. "I tell people: Get in where you fit in."

#### THE BENEFITS OF RESEARCH

Participating in MS research might grant you access to cutting-edge care. You may take a new, potentially better medication before it hits the market or try a possibly beneficial diet or exercise program that you wouldn't have known about otherwise.

You get close monitoring of your health from experts in the field, and it's typically free of charge. Your care could include free education and counseling

that helps you live healthier.

Beyond the personal benefits, Williams says, "You get to help make it better for those with MS who come after you. You help provide understanding and knowledge where we didn't have it before because we didn't have enough diversity in trials."

#### WHAT YOU SHOULD KNOW

Research may require more doctor visits than you normally have. You might have to miss work, arrange childcare, and get support from your family to complete the requirements. It's a big commitment—and a decision you should make with your family.

"Do your research, understand the risks," Williams says. "Then, if you're eligible and it's appropriate for you, everyone is welcome to get involved in research."



# **MEETING THE** CHALLENGE

### What's being done to improve MS care?

By Rachel Reiff Ellis Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

Experts used to believe that MS happened primarily in White people, but recent research shows that MS is more prevalent in Black people than previously thought. MS may also affect Black people differently than it does people who are White.

What's more, some people are less likely to have access to health care or research projects and may face language and cultural differences with the providers they do see.

"Unfortunately, the percentage of Black physicians who are neurologists is very low, and oftentimes, Black patients can be very distrustful of the medical community and the fact that there are not many doctors who look like them," says Stephanie K. Tankou, MD, PhD, assistant professor of neurology at Icahn School of Medicine at Mount Sinai in New York.

#### **FOCUS ON DISEASE DIVERSITY**

Historically, most research on MS in the United States has focused on White adults.

In 2021, the National Institutes of Health (NIH) developed the Minority Health and Health Disparities Strategic Plan to outline a commitment to improving minority health and reducing health disparities.

Tankou, who has participated in grant review processes for the NIH, says the organization is working hard to push the scientific community toward greater diversity in patient populations for clinical trials.

"That's one of the metrics that they are now using to decide if they're going to be funding a study or not," Tankou says. "They specifically require that you show them the ethnicity distribution for your study and what measures you're going to take to ensure that you have good representation, a diverse patient population. And if that's not possible, you need to have a solid justification as to why it's not."

#### **INCREASING ACCESS** AND EDUCATION

Improving MS care in the Black community is getting the message out about the prevalence of the disease, as well as the importance of early detection and treatment.

"I think the biggest problem that I've seen is that many Black patients don't

seek medical attention early enough," Tankou says. "Anything we can do to educate the Black MS community and make them understand that they shouldn't really delay their care is beneficial."

A key piece of not delaying care is improving access to it, both logistically and financially. Tankou says that there are solutions for people who can't pay for medical care. Large MS centers have social workers who help patients navigate financial hurdles, for example.

"A lot of pharmaceutical companies have what's called a free drug program," Tankou says. "And so if a patient doesn't have insurance, which is another common issue that we run into, we can have them apply for the program, so they have access to the treatment they need."



#### Indication

#### What is KESIMPTA (ofatumumab) injection?

KESIMPTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease.

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

#### **Important Safety Information**

#### Who should not take KESIMPTA?

Do NOT take KESIMPTA if you:

- have an active hepatitis B virus (HBV) infection.
- have had an allergic reaction to ofatumumab or life-threatening injection-related reaction to KESIMPTA.

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

KESIMPTA can cause serious side effects such as:

- Infections. Serious infections, which can be life-threatening or cause death, can happen during treatment with KESIMPTA. If you have an active infection, your health care provider (HCP) 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 HCP 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.
- HBV reactivation. If you have ever had HBV infection, it may become active again during or after treatment with KESIMPTA (reactivation). If this happens, it may cause serious liver problems including liver failure

or death. Before starting KESIMPTA, your HCP will do a blood test to check for HBV. They will also continue to monitor you during and after treatment with KESIMPTA for HBV. Tell your HCP right away if you get worsening tiredness or yellowing of your skin or the white part of your eyes.

- 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 HCP 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.

## Before you take KESIMPTA, tell your HCP about all your medical conditions, including if you:

- Have or think you have an infection including HBV or PML.
- 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 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 HCP 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 HCP 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 HCP about what birth control method is right for you during this time.
- Are breastfeeding or plan to breastfeed. It is not known if KESIMPTA passes into your breast milk. Talk to your HCP about the best way to feed your baby if you take KESIMPTA.

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

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.

Please see additional Important Safety Information on back cover and accompanying Consumer Brief Summary on the following page.

#### **Consumer Brief Summary**

The risk information provided here is not comprehensive. This information does not take the place of talking with your doctor about your medical condition or treatment.

To learn more about KESIMPTA (ofatumumab) injections, talk to your doctor or pharmacist. For more information and to obtain the FDA-approved product labeling, call 1-888-669-6682 or visit www.kesimpta.com.

## 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 health care 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 health care 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 health care 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 health care provider will monitor you for HBV infection during and after you stop using KESIMPTA. Tell your health care 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 health care 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 active hepatitis B virus infection.
- have had an allergic reaction to ofatumumab or lifethreatening injection-related reaction to KESIMPTA.

## Before using KESIMPTA, tell your health care 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 had a recent vaccination or are scheduled to receive any vaccinations.
- O You should receive any required 'live' or 'liveattenuated' 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 health care 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 health care 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 health care provider about what birth control
  method is right for you during this time.
- O Pregnancy Registry: There is a registry for women who become pregnant during treatment with KESIMPTA. If you become pregnant while taking KESIMPTA, tell your health care provider right away. Talk to your health care 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
  health care provider about the best way to feed your
  baby if you take KESIMPTA.

Tell your health care 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 health care 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 health care 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 health care 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 health care 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 injections 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 health care provider if you have any of these signs or symptoms.
- o 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 health care provider right away if you experience any of these signs or 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.

🔖 Kesimpta

(ofatumumab) 20 mg injectio

• Low immunoglobulins. KESIMPTA may cause a decrease in some types of antibodies. Your health care provider will do blood tests to check your blood immunoglobulin levels.

#### 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 health care 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.



\*Real-world 30-question survey of 105 US patients (aged ≥18) diagnosed with RMS for 1+ years, who took KESIMPTA with the Sensoready\* Pen within previous 12 months. On a scale of 1-5, 89.5% of patients rated it a 4 or 5 (5 being most positive) on overall ease of use and ease of monthly dosing schedule. Questionnaire not validated.

Typical administration time when ready to inject. Once monthly after 3 weekly starter doses.

#### **Important Safety Information (cont)**

- Use KESIMPTA exactly as your HCP tells you to use it.
- Your HCP 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.

## KESIMPTA may cause serious side effects including:

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· 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 injections 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 to your HCP if you have any of these signs and symptoms.
- o 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 HCP 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,
- Low immunoglobulins. KESIMPTA may cause a decrease in some types of antibodies. Your HCP will do blood tests to check your blood immunoglobulin levels.

#### The most common side effects of KESIMPTA include:

- Upper respiratory tract infection, with symptoms such as sore throat and runny nose, and headache.
- · Headache.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information and the accompanying Consumer Brief Summary inside.



which can be serious.