Your journey with your new medication

You have been prescribed KESIMPTA® to treat your multiple sclerosis (MS). This booklet explains a bit more about your treatment.

The package leaflet that comes with your medicine also contains important information that you should read carefully and keep handy for future reference.

As with any medicine, the more you know about how it works and what to expect, the more confident and prepared you can feel when you start to take it.

Scan this QR code or visit www.kesimpta-connect.ie for further resources and support.

Ask your doctor or nurse if you have any further questions about MS or your treatment.

About your new medicine:

- KESIMPTA® is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (RMS) with active disease.[1]
- It is made of a type of molecule (monoclonal antibody) called ofatumumab, and is intended for you to administer yourself as a subcutaneous (under the skin) injection once-monthly, after the initial dosing period.

How does your treatment work?[2]

B cells are a type of white blood cell that are part of the immune system (the body's defence system) and play a role in MS.

In MS, the immune system attacks the protective layer around nerve cells.

KESIMPTA® works by attaching to a molecule on the surface of certain types of B cells, known as CD20.

It targets and removes these types of B cells.[2]

This in turn can:

- reduce the chance of a relapse
- relieve symptoms
- slow down the progression of the disease

The clinical evidence:

KESIMPTA® was tested in participants with relapsing MS in 2 large clinical studies, that ran for up to 2.5 years.

These studies assessed the effectiveness of the medication and its safety profile, compared with another MS medicine, called teriflunomide.

The safety profile:

KESIMPTA® has been studied for 7 years and counting.

Because safety is so important, this medication continues to be studied in an ongoing extension study where all participants are taking KESIMPTA®.

Like all medicines, side effects can occur, although not everyone will get them.

Learn more about safety and tolerability on page 24.

You can find more information at www.medicines.ie and more information on both studies at www.clinicaltrials.gov. Type NCT02792218 and NCT02792231 into the search box and click "Search".

Before you start any treatment, it's important to understand it's safety profile, potential side effects and clinical evidence.

The clinical evidence:
(continued)

In these studies, compared with teriflunomide, KESIMPTA® was shown to:[1]

Reduce the number of relapses

Overall, the number of relapses experienced decreased from an average rate of 1 relapse per year before the trial, to a rate of 0.1 relapses per year in those treated with KESIMPTA®. A rate of 0.1 relapses per year could mean 1 relapse over 10 years.

Slow disability worsening

Participants with varying degrees of disability took part in the study and disability progression was measured throughout for each individual participant.

Progression was defined as a worsening in disability level from the start of the study that did not improve over a set period of time.

In the pivotal studies, treatment with KESIMPTA® slowed down disability progression more than treatment with teriflunomide.

Things to know before starting treatment:[2]

DO NOT take if:

- **you are allergic to ofatumumab or any of the other ingredients of this medicine (L-arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid [for pH adjustment] and water for injections)**
- **you have been told that you have severe problems with your immune system**
- **you are suffering from a severe infection**
- **you have cancer**

Additional considerations to be aware of:[2]

- Before you start treatment, your doctor may check your immune system. If you are already taking medicines that weaken the immune system, taking KESIMPTA® before or after those medicines may increase your risk of getting infections.
- Infections. If you have an active infection, your doctor may delay your treatment until your infection is gone.
- Hepatitis B (HBV) virus reactivation. If you have ever had an hepatitis B, it may become active again during or after treatment (reactivation). Before starting treatment your doctor will do a blood test to check if you are at risk of hepatitis B infection.