Kesimpta®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using Kesimpta?

Kesimpta contains the active ingredient ofatumumab. Kesimpta is used for the treatment of adults with relapsing forms of multiple sclerosis. For more information, see Section 1. Why am I using Kesimpta? in the full CMI.

2. What should I know before I use Kesimpta?

Do not use if you have ever had an allergic reaction to Kesimpta or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Kesimpta? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kesimpta and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Kesimpta?

- Inject 20mg under the skin on week 0, week 1 and week 2. There is no injection at week 3.
- At week 4 and then every month, inject 20mg under the skin.

More instructions can be found in Section 4. How do I use Kesimpta? in the full CMI. Your health 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 health professional.

5. What should I know while using Kesimpta?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Kesimpta. • Have a blood test to check your liver and for Hepatitis B • Tell your doctor if you have any type of infection • Tell your doctor if you plan to receive a vaccine • Avoid becoming pregnant while using Kesimpta and for 2 months after you stop using it
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• It is not known if Kesimpta will influence your ability to drive and use machines
Drinking alcohol	• There are no known interactions between Kesimpta and alcohol
Looking after your medicine	• Refrigerate, do not freeze. Store between 2°C – 8°C. Keep out of reach of children

For more information, see Section 5. What should I know while using Kesimpta? in the full CMI.

6. Are there any side effects?

Common side effects include upper chest infections (sore throat and runny nose), local injection site reactions such as redness, pain, itching and swelling and general injection site reactions such as fever, headache, muscle pain, chills and tiredness. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Kesimpta®

Active ingredient(s): *ofatumumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kesimpta. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Kesimpta.**

Where to find information in this leaflet:

1. Why am I using Kesimpta?
2. What should I know before I use Kesimpta?
3. What if I am taking other medicines?
4. How do I use Kesimpta?
5. What should I know while using Kesimpta?
6. Are there any side effects?
7. Product details

1. Why am I using Kesimpta?

Kesimpta contains the active ingredient ofatumumab. 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).

Kesimpta is used for the treatment of adults with relapsing forms of multiple sclerosis**.**

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 multiple sclerosis.

2. What should I know before I use Kesimpta?

Warnings

Do not use Kesimpta if:

- you are allergic to ofatumumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- are at risk of hepatitis B infection (all patients will have a blood test before starting Kesimpta)
- are at risk of liver injury (all patients will have a blood test to check your liver before starting Kesimpta)
- have an infection, especially if it is severe. Kesimpta must not be used until a severe infection is better
- have a weakened immune system and are at a higher risk of getting an infection. Kesimpta must not be used until your immune system is stronger
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should avoid becoming pregnant while using Kesimpta and for 2 months after you stop using it.

If you become pregnant or think you are pregnant, tell your doctor right away.

Contraception

To avoid becoming pregnant, you should use contraception while using Kesimpta and for 2 months after you stop using it.

Use in children

- It is not known whether Kesimpta is safe and effective in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Kesimpta and affect how it works.

- Medicines that lower or modify the immune system including other medicines used to treat multiple sclerosis such as ocrelizumab, cladribine, fingolimod, natalizumab, teriflunomide, mitoxantrone, or dimethyl fumarate
- vaccines

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Kesimpta.

4. How do I use Kesimpta?

How much to use

- Inject 20mg under the skin on week 0, week 1 and week 2. There is no injection at week 3.
- At week 4 and then every month, inject 20mg under the skin.

- Follow the instructions provided and use Kesimpta until your doctor tells you to stop.

When to use Kesimpta

- Kesimpta is injected under the skin on week 0, week 1 and week 2. There is no injection at week 3. At week 4 and then every month inject under the skin.

How to use Kesimpta

- Kesimpta is injected under the skin.
- Follow the "Instructions for Use" leaflet in the pack.

If you forget to use Kesimpta

Kesimpta should be used regularly at the same time each week on weeks 0, 1 and 2 and then each month from week 4 onwards.

If you have missed a dose of Kesimpta, you should inject your missed dose as soon as possible without waiting until the next scheduled dose. Any following doses should be administered as per the recommended schedule.

Do not inject a double dose to make up for the dose you missed.

If you use too much Kesimpta

If you think that you have used too much Kesimpta, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Kesimpta?

Things you should do

- **Have a blood test to check for Hepatitis B**
- **Tell your doctor if you plan to receive a vaccine**
- **Avoid becoming pregnant while using Kesimpta and for 2 months after you stop using it**

Call your doctor straight away if you:

- Have injection related reactions or injection site reactions
- Have any type of infection
- Believe your multiple sclerosis is getting worse (e.g. weakness or eye changes) or if you notice any new or unusual symptoms – this can be serious.
- Have symptoms of an allergic reaction including rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, feeling faint.
- If any of these symptoms become worse or you have new serious symptoms after more injections.

Remind any doctor, dentist or pharmacist you visit that you are using Kesimpta.

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Kesimpta affects you.

The effects of Kesimpta on a person's ability to drive and use machines has not been tested.

Looking after your medicine

- Store between 2 to 8°C. Refrigerate. Do not freeze. Keep in the original package.
- If necessary, Kesimpta may be stored unrefrigerated 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Upper chest infections such as: • sore throat • runny nose **Local injection site reactions such as:** • redness • pain • itching • swelling at injection site **General injection site reactions such as:** • fever • headache • muscle pain • chills	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.**

Less serious side effects	What to do
• tiredness **Infections such as:** • urinary tract infection	

Serious side effects

Serious side effects	What to do
Worsening of multiple sclerosis symptoms such as: • muscle weakness, muscle stiffness, muscle spasms • eye changes such as blurred vision, double vision • tremor • general weakness or • any unusual or different symptoms **Allergic reaction symptoms such as:** • rash • hives • trouble breathing • swelling of the face, eyelids, lips, mouth, tongue or throat • chest tightness • feeling faint **Other symptoms such as:** • new or worsening tiredness, anorexia, feeling sick, vomiting, right upper tummy discomfort, dark urine, or yellowing of the skin	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects (for example decrease in specific proteins in the blood (immunoglobulins M) which help protect against infection) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Kesimpta contains

Active ingredient (main ingredient)	Each injection contains ofatumumab 20 mg
Other ingredients (inactive ingredients)	arginine sodium acetate trihydrate sodium chloride polysorbate 80 disodium edetate hydrochloric acid water for injection

Do not administer this medicine if you are allergic to any of these ingredients.

What Kesimpta looks like

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

This product contains only one pre-filled pen or pre-filled syringe per pack.

The single-use solution for injection is sterile, preservative-free, clear to slightly opalescent, and colorless to slightly brownish-yellow (Aust R 330617; AUST R 330601).

*Not all products may be marketed

Who distributes Kesimpta

Kesimpta is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

(ABN 18 004 244 160)

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

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