Package Leaflet: Information for the patient

LEQEMBI 100 mg/mL concentrate for solution for infusion
lecanemab

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start receiving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LEQEMBI is and what it is used for

What LEQEMBI is
LEQEMBI contains the active substance lecanemab. Lecanemab is a monoclonal antibody. Antibodies are found naturally in our blood and help us to fight infection. Monoclonal antibody therapies mimic natural antibodies but are made in a laboratory. They work by binding to a target protein to reduce the harmful effect of that protein. Lecanemab binds to a protein called *amyloid beta*, which is involved in Alzheimer's disease.

What LEQEMBI is used for
LEQEMBI is used to treat the early stages of Alzheimer's disease in adults who carry one copy of a gene called apolipoprotein E4, also known as ApoE4, or in adults who do not carry this gene.

Your healthcare provider will perform testing to make sure that LEQEMBI is right for you.

What is Alzheimer's disease
Alzheimer's disease is an illness that affects the brain. Communications between brain cells become blocked due to amyloid beta plaques. This eventually leads to problems with memory, thinking and behaviour. Alzheimer's disease symptoms can be different for everyone. Symptoms usually develop slowly and get worse over time, becoming severe enough to interfere with daily tasks.

In Alzheimer's disease, clumps of amyloid beta protein form plaques in the brain. LEQEMBI works by binding to these clumps and reducing them. This slows down progression of early Alzheimer's disease.

2. What you need to know before you are given LEQEMBI

You must not be given LEQEMBI
- If you are allergic to lecanemab or any of the other ingredients of this medicine (listed in section 6).
- If your Magnetic Resonance Imaging (MRI) brain scan shows small spots of bleeding or fluid in the brain, or evidence of larger bleeding in the past.
- If you are receiving medicines (called anticoagulants) to prevent blood clots.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given LEQEMBI if any of the following apply to you:

- you have had a mini stroke, stroke or seizure (fit) within the last 12 months.
- you have a bleeding disorder.
- you have Down syndrome.

Allergic reactions

Tell your doctor or nurse straight away if you develop any signs or symptoms of an allergic reaction during or after you are given LEQEMBI. See section 4 "Possible side effects" for signs of an allergic reaction.

Amyloid related imaging abnormalities (ARIA)

LEQEMBI can cause a side effect called amyloid related imaging abnormalities, or "ARIA". ARIA is a side effect that does not usually cause any symptoms, but serious symptoms, including life-threatening symptoms can occur. ARIA is most commonly seen as temporary swelling in one or more areas of the brain (*ARIA-E*) that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain (*ARIA-H*), and infrequently, larger areas of bleeding in the brain can occur. Most people with ARIA do not get symptoms, however some people may have symptoms, such as:

- Headache
- Confusion
- Dizziness
- Vision changes
- Feeling sick (nausea)
- Difficulty walking
- Fits (seizures)

Tell your doctor or nurse if you experience any of these symptoms.

ARIA-E and ARIA-H are visible on a Magnetic Resonance Imaging (MRI) brain scan. The MRI uses magnetic waves to create detailed images of the soft tissues of the body. Your doctor will do MRI scans before and during your treatment with LEQEMBI to check you for ARIA.

Genetic Risk Factors for ARIA

Some people carry a gene called ApoE4 that increases the risk for ARIA, particularly in people that have 2 copies of the gene (homozygous ApoE4 carriers). Your doctor will discuss this with you and arrange a genetic test to make sure that LEQEMBI is suitable for you.

Infusion-related reactions

Infusion-related reactions are a very common side effect of LEQEMBI treatment. **Tell your doctor or nurse straight away** if you experience any symptoms associated with your LEQEMBI infusion. For symptoms, see section 4 "Possible side effects". Most infusion-related reactions occur during the infusion or within 2.5 hours after the infusion is completed. If you have an infusion-related reaction, you may be given medicines before your infusions to decrease your chance of having an infusion-related reaction. These medicines may include antihistamines, paracetamol, anti-inflammatory medicines or steroids.

Medicines used to prevent or dissolve blood clots

The risk of having a larger bleed in the brain (known as intracerebral haemorrhage) with LEQEMBI treatment is increased in patients receiving medicines used to prevent blood clots (anticoagulants) or to dissolve them (thrombolytic agents). **Tell your doctor** that you are being treated with LEQEMBI before you receive any medication to prevent blood clots or dissolve them. LEQEMBI can be used together with aspirin and other medicines that prevent your blood cells sticking together (antiplatelet agents).

Children and adolescents
LEQEMBI is not for use in children and adolescents aged less than 18 years because Alzheimer's disease does not occur in this age group.

Other medicines and LEQEMBI
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular tell your doctor:

- If you are taking medicines (called anticoagulants) that prevent blood clots. LEQEMBI should not be used with these medicines.

LEQEMBI can be used alone, or together with other medicines that treat symptoms of Alzheimer's disease.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. It is not known if LEQEMBI will harm your unborn baby or if this medicine passes into breast milk.

If you become pregnant while you are using LEQEMBI, tell your doctor. You and your doctor can discuss if you should carry on with treatment.

If you are breast-feeding, you and your doctor can discuss if you should carry on with breast-feeding or treatment.

Using contraception
Your doctor should advise you about using contraception during treatment with LEQEMBI and up to 3 months after the last dose of LEQEMBI.

Driving and using machines
Some patients may experience symptoms such as dizziness or confusion. This could affect the ability to drive and use machines. Do not drive or use tools or machinery until you feel better.

3. How LEQEMBI is given

LEQEMBI will be given to you under the supervision of a healthcare professional.

LEQEMBI is given as a 'drip' (a needle placed in your vein) also called an intravenous (IV) infusion. Each infusion will last approximately 1 hour.

Dosage
The recommended dose is 10 milligrams per kilogram of your body weight (mg/kg). It should be given to you every 2 weeks.

Your doctor will arrange MRI scans before your fifth, seventh and fourteenth doses of LEQEMBI. This is routine monitoring to check if you have ARIA. Additional scans can be performed at other times during treatment if your doctor thinks you need them.

Your doctor may pause or stop treatment, depending on your MRI results.

If you miss an infusion of LEQEMBI
If you miss an infusion of LEQEMBI, talk to your doctor to arrange to have it as soon as possible. Do not wait until your next planned infusion.

When to stop using LEQEMBI
Your doctor may recommend pausing or stopping treatment, depending on your clinical test results.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported with LEQEMBI:

Serious side effects

Immediately tell the healthcare professional giving you LEQEMBI if you notice any signs of an allergic reaction while or shortly after you are given this medicine. Signs of an allergic reaction include swelling of the face, lips, mouth or tongue, hives or difficulty breathing.

Uncommon side effects (may affect up to 1 in 100 people)
– Areas of larger bleeds in the brain (known as intracerebral haemorrhages).

Other side effects

Very common side effects (may affect more than 1 in 10 people)
- Small spots of bleeding in or on the surface of the brain (ARIA-H) (see section 2 "What you need to know before you are given LEQEMBI" for more information on ARIA-H).
- Infusion-related reactions. Signs include fever, flu-like symptoms such as chills, body aches, feeling shaky and joint pain, feeling sick (nausea), being sick (vomiting), dizziness or light-headedness, changes in your heart rate or feeling like your chest is pounding, difficulty breathing or shortness of breath.
- Headache.

Common side effects (may affect up to 1 in 10 people)
- Swelling in areas of the brain (ARIA-E) (see section 2 "What you need to know before you are given LEQEMBI" for more information on ARIA-E).
- Abnormal heart rhythm (atrial fibrillation). Signs of this can include irregular heartbeat (racing or fluttering in your chest), chest pain, shortness of breath, dizziness or feeling faint, tiredness, or finding it harder to exercise.
- Rash.

Talk to your doctor about how to manage these side effects.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play and Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LEQEMBI

LEQEMBI will be stored by healthcare professionals.

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the vial label after 'EXP'. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C). Do not freeze or shake.
- Store in the original package in order to protect from light.
- After dilution, an immediate use is recommended. Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. However, from a microbiological point of view, unless the method of dilution precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6. Contents of the pack and other information

What LEQEMBI contains
- The active substance is lecanemab. Each mL of concentrate contains 100 mg lecanemab.
- The other ingredients are histidine hydrochloride monohydrate, arginine hydrochloride, polysorbate 80, and water for injections.

What LEQEMBI looks like and contents of the pack

LEQEMBI is a clear to slightly opalescent and colourless to pale yellow concentrate for solution for infusion that comes in a glass vial.

LEQEMBI is available in packs containing 1 vial.

1 vial packs
These contain either 2 mL or 5 mL.

Marketing Authorisation Holder

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United Kingdom

Manufacturer

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The following information is intended for healthcare professionals only:

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

See section 3 for Posology of the medicine.

Instructions for preparation

LEQEMBI is for single use only.

LEQEMBI is a concentrate and must be diluted prior to infusion.

Calculating the dose
More than one vial of LEQEMBI concentrate may be needed to give the total dose for the patient.

The prescribed dose for the patient is given in mg/kg (see section 3). Based on this prescribed dose, calculate the total dose to be given.

The total LEQEMBI dose in mg = the patient's weight in kg × the prescribed dose in mg/kg.

The volume of LEQEMBI concentrate to prepare the dose (mL) = the total dose in mg, divided by 100 (the LEQEMBI concentrate strength is 100 mg/mL).

Preparing the LEQEMBI infusion
Aseptic technique should be used when preparing the LEQEMBI diluted solution for intravenous infusion.

- Check that the LEQEMBI liquid is clear to slightly opalescent and colourless to pale yellow.
- Withdraw the required volume of LEQEMBI from the vial(s) and add to 250 mL 0.9% sodium chloride solution for injection.
- Gently invert the infusion bag containing the LEQEMBI diluted solution to mix completely. Do not shake.
- After dilution, an immediate use is recommended. Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. However, from a microbiological point of view, unless the method of dilution precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
- Prior to infusion, allow the LEQEMBI diluted solution to warm to room temperature.
- Any unused product or waste material should be disposed of in accordance with local requirements.

Method of administration
LEQEMBI is for intravenous use only.

LEQEMBI must not be administered as an intravenous push or bolus injection.

LEQEMBI is diluted prior to intravenous infusion (as per above instructions for preparation). The diluted medicinal product should be visually inspected for particles or discolouration prior to administration. Do not use if it is discoloured or if opaque particles are seen.

The diluted solution is infused through an intravenous line over approximately 1 hour. Use of a sterile, low-protein binding micron in-line filter (0.2 micron to 15 micron pore size) is recommended.

Patients should be observed during the infusion. The infusion must be promptly discontinued upon the first observation of any signs or symptoms consistent with a hypersensitivity-type reaction.