

A photograph of two women walking through a cobblestone city square. The woman on the left is wearing a pink blazer and blue jeans, while the woman on the right is wearing a white sweater and black pants. A vibrant, multi-colored light trail (rainbow spectrum) flows behind them from left to right. In the background, there is a large, curved, light-colored stone building with several windows. A white circular graphic in the top right corner contains the text 'AJOVY (fremanezumab) injection 225 mg/1.5 mL'.

AJOVY™
(fremanezumab)
injection 225 mg/1.5 mL

AJOVY® Patient Information Booklet

This information is for adults who have been diagnosed with migraine and prescribed AJOVY (fremanezumab). It is important to know what to expect while being treated with AJOVY. This booklet provides answers to some common questions about AJOVY but should not replace the advice of your doctor. If you have any concerns about your treatment or condition, you should talk to your doctor.

teva

The AJOVY® story

This booklet is designed to give you a better understanding of how AJOVY works to prevent migraine.

What is AJOVY?¹⁻³

AJOVY is a prescription medicine used to prevent migraine in adults. It comes in a Pre-filled syringe with a fixed injection needle or an Autoinjector.

AJOVY is approved for the treatment of migraine with quarterly or monthly dosing options.

Quarterly dosing is 3 x 225 mg subcutaneous (under the skin) injections given on one day every 3 months. **Monthly dosing** is 1 x 225 mg subcutaneous injection each month, on the same date each month.

AJOVY is PBS listed in Australia for the treatment of patients with chronic or high-frequency episodic migraine (>7 days per month).⁴

AJOVY Momentum Program

Patients not eligible for PBS can still access AJOVY through the **Momentum Program**.

For further information on the AJOVY Momentum Program, contact TEVA Australia Customer Service on 02 8061 9928 or email: customerservice.au@tevapharm.com

How AJOVY works¹⁻³

The active ingredient in AJOVY is fremanezumab, which is a type of protein that recognises and binds to a specific target in the body: the calcitonin gene-related peptide (CGRP). AJOVY binds to the CGRP, thereby blocking it from binding to the CGRP receptor. CGRP plays an important role in migraine.

AJOVY has been shown to reduce the frequency of migraine attacks and days with headache. Other important migraine-associated symptoms such as nausea, vomiting and sensitivity to light and sound have also been shown to reduce in some patients treated with AJOVY.

You'll find more details in the Consumer Medicines Information (CMI) leaflet available from your doctor, nurse or pharmacist or from the MigraineHQ website, www.migrainehq.com.au

Before you use AJOVY

Tell your doctor:¹⁻³

- **IF YOU ARE ALLERGIC** or sensitive to fremanezumab, to any of the ingredients listed in the Consumer Medicines Information (CMI) leaflet; any similar medicines (such as medicines of the same class or with a similar structure).

- **IF YOU ARE PREGNANT**, you think you may be pregnant, you are planning to have a baby, you are breastfeeding or planning to breastfeed. It is preferable to avoid the use of AJOVY® during pregnancy as the effects of this medicine in pregnant women are not known. Your doctor can explain the risks and benefits.
- **IF YOU ARE TAKING** any other medicines, whether they are prescription medications or those you can buy over the counter.

Present immediately to the emergency department of your local hospital if you experience symptoms of allergic reaction.

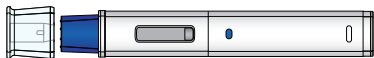
- **Symptoms of an allergic or hypersensitivity reaction may include:**

- chest tightness, cough, wheezing or difficulty breathing
- drop in blood pressure (fainting, dizziness, feeling lightheaded)
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- stomach pain or discomfort
- vomiting.

Before you start injecting AJOVY

Before you start using AJOVY, please review the full “Instructions For Use” leaflet that comes with your Pre-filled syringe or Autoinjector.

Autoinjector



Pre-filled syringe



For more information on how to inject, including video guidance, use the QR code here or go to www.migraineHQ.com.au and follow the instructions to log in.

If you still have any questions after reading these instructions or watching the instructional video, please talk to your doctor or pharmacist.

Please take note¹⁻³

- The AJOVY® Pre-filled syringe and Autoinjector are for single use only.
- AJOVY is injected under your skin (subcutaneous injection). Do not inject AJOVY into your veins (intravenously).
- Do not inject yourself until you have been trained by your doctor or a nurse and feel confident to do so. Your caregiver must also be trained before they can give you injections.
- AJOVY should be stored in the fridge. (2 degrees Celcius to 8 degrees Celcius). Do not freeze.
- Before injecting, wait for 30 minutes to let AJOVY reach room temperature. This will reduce discomfort during injection.
- Once you have injected AJOVY, do not put the protective cap back on the used syringe or Autoinjector.
- Discard the used syringe or Autoinjector right away in an approved, puncture-resistant sharps container and keep out of the reach of children.
- If using the Pre-filled syringe, do not pull back on the plunger at any time as this can break the Pre-filled syringe.
- Do not re-use your AJOVY Pre-filled syringe or Autoinjector.
- Do not give your medicine to anyone else, even if they have the same condition as yours.

How to use your AJOVY Autoinjector or Pre-filled syringe¹⁻³

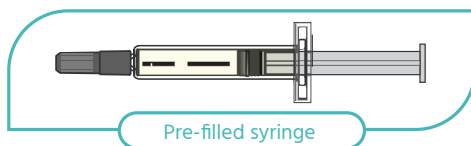
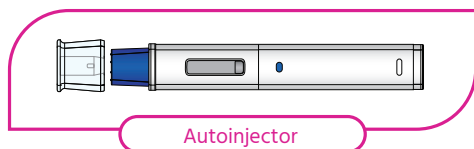
Please keep your AJOVY in the fridge after you receive it

Step 1 Take AJOVY out of the fridge to reach room temperature

- Wait for 30 minutes to let AJOVY reach room temperature to reduce discomfort during injection.
- Gather supplies for your injection:
 - 1 or 3 AJOVY injections, depending on your prescribed dose (monthly or quarterly)
 - 1 alcohol swab per injection
 - 1 gauze pad or cotton ball per injection
 - 1 sharps disposal or puncture-resistant container.

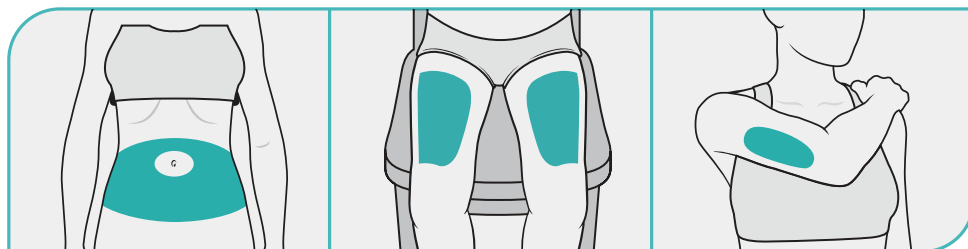


Step 2 Inspect your AJOVY Autoinjector or Pre-filled syringe



- Check the name and that your medication is not out of date.
- Check that the liquid looks clear and is colourless to slightly yellow.
- You may see small air bubbles. This is normal.

Step 3 Choose your injection area and clean with alcohol swab

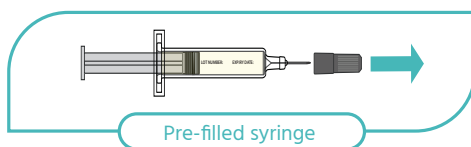
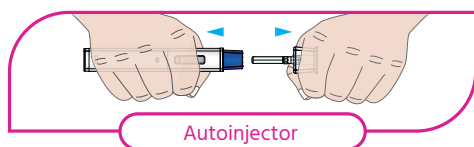


Abdomen: about 5 cm around the belly button

Thighs: about 5 cm above the knee and 5 cm below the groin

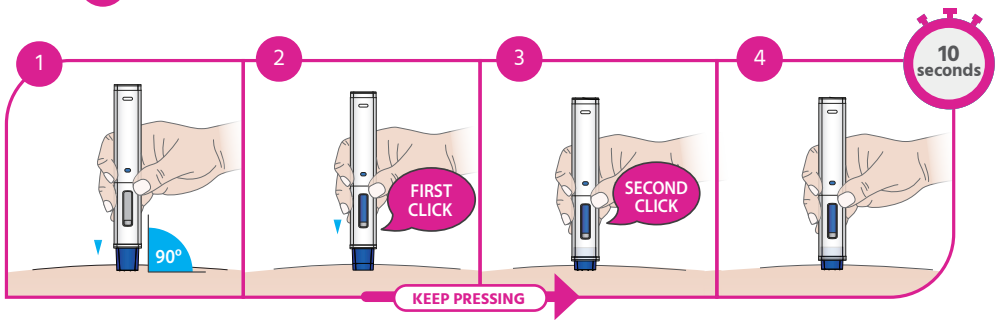
Back of upper arms

Step 4 Remove the protective cap



- Pick up your Autoinjector or Pre-filled syringe with one hand and pull the protective cap straight off with the other, elbows out. You may encounter some resistance, but this is normal. Do not twist nor attempt to replace the cap at any time. Once the cap has been removed, your device is ready to use.
- Do not put the protective cap back on.

Step 5 Administer your injection – Autoinjector



1 Place the Autoinjector at a 90-degree angle against your cleaned skin at the injection site. Press down and continue pressing down for about 30 seconds until all the steps shown are complete.

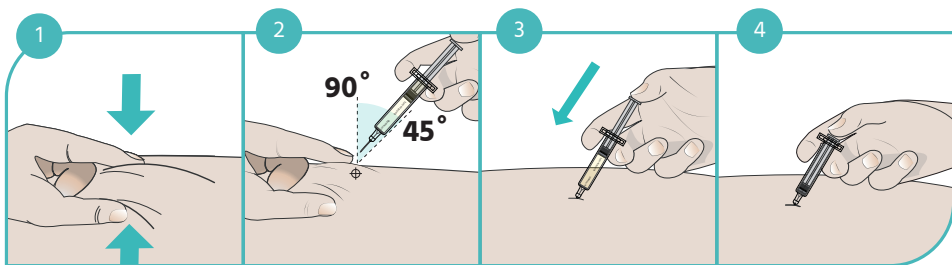
2 You will hear the first “click”. This signals the start of the injection, and the blue plunger starts to move. Keep the device pressed down against your skin.

3 You will hear a second “click” about 15 seconds after the first “click”. The plunger will be moving to the bottom of the viewing window as the medicine is being injected.

4 Wait another 10 seconds to make sure all of the medicine is injected.

For questions about AJOVY® or injecting, please talk to your doctor.

Step 5 Administer your injection – Pre-filled syringe



1 Gently pinch at least 2.5 cm of the skin.

2 Insert the needle into the pinched skin at an angle of 45–90 degrees.

3 Slowly push the plunger in.

4 Push the plunger all the way down as far as it will go to inject all the medicine.

Step 6 Remove the Autoinjector or Pre-filled syringe needle from your skin

- Apply pressure at injection site with cotton ball or gauze for a few seconds.

Step 7 Dispose of the Autoinjector or Pre-filled syringe

- Dispose of AJOVY® into a sharps container. **DO NOT** recap AJOVY.
- Ask your doctor, pharmacist or nurse how to throw away the container when full.

If your dose is 675 mg, repeat the steps with the second and third injection to inject the full dose. Avoid injecting in exactly the same place each time.





What dose should I give?

Your doctor will prescribe AJOVY® either once a month (monthly dosing) or once every three months (quarterly dosing) after deciding which dosing regimen is best for you.

The **monthly dose** is 225 mg (1 Pre-filled syringe or Autoinjector).

The **quarterly dose** is 675 mg (3 Pre-filled syringes or Autoinjectors, given at the same session at three different sites).

If your doctor decides to change your dosing regimen, use your first new dose on the scheduled dosing date for the previous regimen.

How long will I be using AJOVY?

AJOVY helps control your condition but is not a cure, so you should keep taking it for as long as your doctor recommends, even if you feel well. It's a good idea to make an appointment to see your doctor after 8–12 weeks to discuss whether or not you should continue.¹⁻³

What happens if I miss a dose?¹⁻³

- If you forget to inject a dose, give your missed dose as soon as possible.
- DO NOT take a double dose to make up for a missed dose.
- If in doubt, contact your doctor or pharmacist for advice.

What if I give myself too much?

If you think you or someone else has used too much AJOVY®, phone your doctor or the Poisons Information Centre (13 11 26) immediately or go to the accident and emergency department at your nearest hospital – even if there are no signs of discomfort or poisoning. You may need urgent medical attention.¹⁻³

What are the possible side effects of AJOVY?¹⁻³

Like all medicines, AJOVY can cause side effects. The side effects caused by AJOVY are usually mild to moderate and you may not experience any of them. Ask your doctor or pharmacist any questions you may have.

The most common side effects include local skin reactions at the injection site.

AJOVY may cause serious side effects including allergic reactions. If you think you are having an allergic reaction to AJOVY, stop using this medicine and contact your doctor or nurse immediately or go to the accident and emergency department at your nearest hospital. Symptoms of an allergic or hypersensitivity reaction may include: chest tightness, cough, wheezing or difficulty breathing; drop in blood pressure (fainting, dizziness, feeling lightheaded); swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; stomach pain or discomfort; vomiting.

Tell your doctor or pharmacist as soon as possible if you do not feel well while using AJOVY.

How to store AJOVY¹⁻³

- **Store AJOVY in your fridge at a temperature between 2°C and 8°C.**
- Do not freeze AJOVY.
- You can store AJOVY outside your fridge for up to 7 days at up to 30°C.
- Discard AJOVY if not used within 7 days of removal from your fridge.
- Keep the Pre-filled syringe(s) or Autoinjector(s) in the outer carton to protect from light.
- Do not shake the Pre-filled syringe or Autoinjector.
- Do not store AJOVY in the bathroom, near a sink, on a windowsill or in a car.
- Store AJOVY where children cannot reach it.

References: **1.** AJOVY® (fremanezumab) Consumer Medicines Information, August 2023. **2.** AJOVY® Pre-filled syringe Instructions for Use leaflet. **3.** AJOVY® Autoinjector Instructions for Use leaflet. **4.** Pharmaceutical Benefits Scheme. AJOVY. Available at: <https://www.pbs.gov.au/medicine/item/12603H-12611R-13115G-13129B> (Accessed January 2024).

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