AJOVY®

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 AJOVY?

AJOVY contains the active ingredient fremanezumab. AJOVY is used to prevent migraine in adults and to prevent episodic migraine (between 4 and 14 migraine days per month) in children aged 6 years and older who weigh at least 45 kg.

For more information, see Section 1. Why am I using AJOVY? in the full CMI.

2. What should I know before I use AJOVY?

Do not use if you have ever had an allergic reaction to AJOVY 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 AJOVY? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AJOVY 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 AJOVY?

- Follow all directions given to you by your doctor or pharmacist carefully.
- AJOVY must only be given by subcutaneous injection.

More instructions can be found in Section 4. How do I use AJOVY? in the full CMI.

5. What should I know while using AJOVY?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using AJOVY.

	• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not take AJOVY to treat any other complaints unless your doctor tells you to. • Do not administer AJOVY by any other method or route other than subcutaneous injection.
Driving or using machines	• Be careful driving or operating machinery until you know how AJOVY affects you.
Looking after your medicine	• Store in a refrigerator (2°C to 8°C). Do not freeze. • AJOVY may be stored unrefrigerated for up to 7 days at a temperature up to 30°C.

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

6. Are there any side effects?

Less serious side effects: Local skin reactions at the injection site: pain, hardening or redness; itching; rash.

Serious side effects: 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.

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 due to approval of an extension of indications. 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.

AJOVY® (A-JO-VEE)

Solution for Injection

Active ingredient(s): Fremanezumab (Fre-ma-nay-zoo-mab)

Consumer Medicine Information (CMI)

This leaflet provides important information about using AJOVY. **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 AJOVY.**

Where to find information in this leaflet:

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

1. Why am I using AJOVY?

AJOVY is a medicine containing the active substance fremanezumab, a monoclonal antibody, a type of protein that recognises and binds to a specific target in the body.

AJOVY is used to prevent migraine in adults.

AJOVY is used to prevent episodic migraine (between 4 and 14 migraine days per month) in children aged 6 years and older who weigh at least 45 kg.

Fremanezumab, which belongs to the anti-CGRP class of medications, binds to the calcitonin gene-related peptide (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. This medicine also decreases important migraine-associated symptoms like nausea, vomiting, sensitivity to light and sound.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

2. What should I know before I use AJOVY?

Warnings

Do not use AJOVY if:

- you are allergic to fremanezumab, or any of the ingredients listed at the end of this leaflet.
- you are using any other similar medicines (such as medicines of the same class or with a similar structure).
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic 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 if you have or have had cardiovascular disease (problems affecting the heart and blood vessels) before using this medicine, because AJOVY has not

been studied in patients with certain cardiovascular diseases.

Development of high blood pressure and worsening of pre-existing high blood pressure have been reported following the use of anti-CGRP class of medications including Ajovy in the post-marketing setting.

Do not take this medicine if the packaging is torn or shows signs of tampering.

Check the pre-filled syringe or autoinjector label and the box. Make sure the name AJOVY appears on the label.

If you are not sure whether you should start taking this medicine, talk to your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking AJOVY.

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.

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 discuss with you the risks and benefits involved.

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.

It is not yet known whether some medicines and AJOVY may interfere with each other and affect how each might work.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Tell your doctor if you are taking any medication to prevent migraines.

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

4. How do I use AJOVY?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

AJOVY is given by single use needle injection using a pre-filled syringe or autoinjector, into the tissues just below the skin.

This is called a subcutaneous injection and it is a simple procedure.

AJOVY must only be given by subcutaneous injection in areas such as:

- **the stomach area (abdomen)**
- **front of your thighs**
- **the back of your upper arms**

AJOVY can be given by your doctor and/or caregivers. You may also be able to inject yourself once you have received the correct training and are confident in doing so.

In children aged 6 to 12 years, AJOVY must be given by your doctor and/or caregivers.

It is important that neither you nor a caregiver try to administer the injection unless you have received training from your doctor or nurse.

If you and/or your caregiver do not understand the instructions in this leaflet or the "Instructions for Use" leaflet, ask your doctor or pharmacist for help.

Each pre-filled syringe or autoinjector is for single use in one patient only.

Wait for 30 minutes to let AJOVY reach room temperature to reduce discomfort during injection.

Do NOT leave the pre-filled syringe or autoinjector in direct sunlight.

Do NOT warm up the pre-filled syringe or autoinjector using a microwave or any other heat source.

Do NOT pull back the plunger at any time as this can break the pre-filled syringe.

Do NOT shake the pre-filled syringe or autoinjector.

Do NOT use this medicine if you notice that the pre-filled syringe or autoinjector is damaged, or that the medicine is cloudy, discoloured or there are particles in it.

Do NOT use this medicine after the expiry date which is stated on the outer carton and on the label of the pre-filled syringe or autoinjector after EXP. The expiry date refers to the last day of that month.

How much to take /When to take AJOVY

AJOVY can be given to adults as either:

- 225 mg once monthly (monthly dosing) equivalent to one pre-filled syringe or autoinjector; or
- 675 mg every three months (quarterly dosing) equivalent to three pre-filled syringes or autoinjector given in a single sitting at three different injection sites.

AJOVY can be given to children aged 6 years and older weighing at least 45 kg as:

- 225 mg once monthly (monthly dosing) equivalent to one pre-filled syringe or autoinjector.

Your doctor will advise which dosing regimen is right for you.

If your doctor advises you that they are switching dosing regimens, the first dose of the new regimen should be administered on the next scheduled dosing date of the prior regimen.

If you or a caregiver is administering AJOVY refer to the "Instructions for Use" leaflet for correct clean injection technique and preferred injection sites.

It may be helpful to use a reminder method such as a calendar or diary to help you remember your next dose so that you avoid missing or repeating doses.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

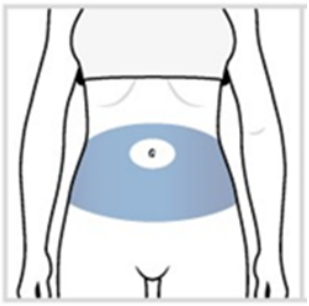
You should see your doctor after you have been using AJOVY for 8-12 weeks to discuss whether you should keep using AJOVY.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

How to Administer AJOVY

Choose an injection area from the following areas:

- **Your stomach area (abdomen), avoid about 5 cm around the belly button**



- **The front of your thighs, about 5 cm above the knee and 5 cm below the groin**



- **The back of your upper arms, in the fleshy areas of the upper back portion**



If multiple injections are required, they may be given in the same or different area (abdomen, thigh, upper arm) but you should avoid injecting in exactly the same place.

If you forget to use AJOVY

If you have missed a dose of AJOVY, inject your missed dose as soon as you can.

Do not take a double dose to make up for a forgotten dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your doctor or pharmacist for some hints.

If you use too much AJOVY

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

You should immediately:

- phone the Poisons Information Centre **(In Australia by calling 13 11 26 and in New Zealand 0800 POISON [0800 764 766])**, 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 AJOVY?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking AJOVY.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect or be affected by other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

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

Things you should not do

Do not take AJOVY to treat any other complaints unless your doctor tells you to.

Do not co-administer AJOVY with other injectable drugs at the same injection site.

Do not administer AJOVY by any other method or route other than subcutaneous injection using the technique as demonstrated by your doctor in accordance with this leaflet or the separate "Instructions for Use guide". Speak to your doctor if you are unsure.

Do not administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are:

- tender

- bruised
- sunburnt
- hardened
- red
- infected
- tattooed
- calloused
- scarred; or
- contain stretch marks
- For multiple injections, do not use the same injection site.

Refer to the "Instructions for Use" leaflet with this medicine for helpful hints on where you should inject if you are unsure.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine without checking with your doctor.

Driving or using machines

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

Looking after your medicine

Storage

Store in a refrigerator (2°C to 8°C).

Do not freeze.

AJOVY may be stored unrefrigerated for up to 7 days at a temperature up to 30°C.

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

Store in the original carton in order to protect from light.

Do not store AJOVY:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Disposal

Once you have injected AJOVY, do not put the needle cap back on the used syringe.

Discard the used pre-filled syringe or autoinjector right away into an approved, puncture-resistant sharps container and keep it out of the reach of children.

Never put the used pre-filled syringes/autoinjectors or sharps disposal container into your normal household rubbish bin or recycling container.

Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

When to discard your medicine

AJOVY must be discarded if not used within 7 days of removal from refrigeration.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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 printed on the pack.

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. The side effects caused by AJOVY are usually mild to moderate.

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
Local skin reactions at the injection site: • pain, hardening or redness	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• itching • rash **Gut-related** • constipation **Other** • fatigue • high blood pressure or worsening of high blood pressure	

Serious side effects

Serious side effects	What to do
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	**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.**

Serious side effects	What to do
• rash, itching or hives on the skin • stomach pain or discomfort • vomiting	

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.

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 or Medsafe at https://pophealth.my.site.com/carmreportnz/s/. 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 AJOVY contains

Active ingredient **(main ingredient)**	Each pre-filled syringe of AJOVY contains 225 mg of fremanezumab as the active ingredient in 1.5 mL of solution (150 mg/mL). Each autoinjector of AJOVY contains 225 mg of fremanezumab as the active ingredient in 1.5 mL of solution (150 mg/mL).
Other ingredients **(inactive ingredients)**	• Histidine • Histidine hydrochloride monohydrate • Sucrose • Disodium edetate • Polysorbate 80 • Water for injections

AJOVY does not contain lactose or gluten.

AJOVY does not contain any preservatives.

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

What AJOVY looks like

AJOVY is a solution for injection. It is supplied in a pre-filled syringe with a fixed injection needle in a blister, or in an autoinjector.

AJOVY is a clear, colourless to slightly yellow solution.

Each pre-filled syringe contains 1.5 mL solution.

Pre-filled Syringe:

AJOVY is available in packs containing 1 or 3 pre-filled syringes.

225 mg/1.5 mL pre-filled syringe: Aust R 308630

Autoinjector:

AJOVY is available in packs containing 1 or 3 autoinjector(s) containing an integrated pre-filled syringe.

225 mg/1.5 mL autoinjector: Aust R 342612

Not all pack sizes may be marketed.

Autoinjector not currently available in New Zealand.

Who distributes AJOVY

AJOVY is supplied in Australia by:

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Rd

Macquarie Park, NSW, 2113

Toll Free Number: 1800 288 382

Distributed in New Zealand by:

Teva Pharma New Zealand Ltd

PO Box 128 244, Remuera

Auckland 1541,

New Zealand

Telephone: 0800 800 097

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