

▼ 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.

AJOVY (A-JO-VEE)®

Fremanezumab (Fre-ma-nay-zoo-mab)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AJOVY. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AJOVY against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AJOVY is used for

AJOVY is used to prevent migraine in adults.

Do not give this medicine to a child or adolescent under the age of 18 years.

AJOVY is not recommended for children and adolescents below the age of 18 years because it has not been studied in this age group.

How it works

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.

Fremanezumab 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.

Before you use AJOVY

When you must not take it

Do not take AJOVY if you have an allergy or are sensitive to:

- fremanezumab
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines (such as medicines of the same class or with a similar structure)

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

Before you start to take it

- **Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. 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.

- **Talk to your doctor if you are breast-feeding or are planning to breast-feed.**

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Check the syringe 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you can get 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.

How to take 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 prefilled syringe, 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.

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 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 in direct sunlight.

Do NOT warm up the pre-filled syringe 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.

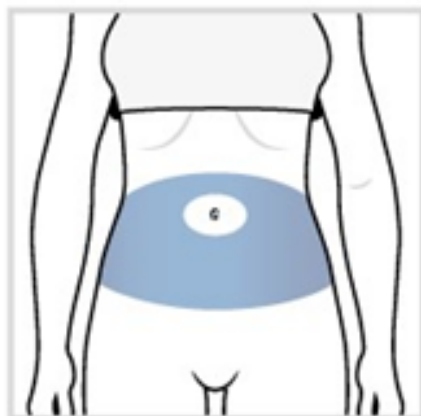
Do NOT use this medicine if you notice that the syringe is damaged, or that the medicine is cloudy, discoloured or there are particles in it.

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 after EXP. The expiry date refers to the last day of that month.

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.

How much to take/When to take it

AJOVY can be given as either:

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

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.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much AJOVY. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using AJOVY

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how AJOVY affects you.

Side Effects

Like all medicines, AJOVY can cause side effects, although not everybody gets them. The side effects caused by AJOVY are usually mild to moderate.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AJOVY. You may be advised to stop taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Common side effects

Very common (may affect more than 1 in 10 people):

- Local skin reactions at the injection site: pain, hardening or redness

Common (may affect up to 1 in 10 people):

- Local skin reactions at the injection site: itching

Uncommon side effects

Uncommon (may affect up to 1 in 100 people):

- Local skin reactions at the injection site: rash
- **If you get any side effects, talk to your doctor or pharmacist. This also includes any possible side effects not listed above.**
- **Tell your doctor if you notice anything that worries you or is making you feel unwell.**

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

Storage and Disposal of AJOVY

Storage

Store in a refrigerator (2°C to 8°C).

Do not freeze.

AJOVY may be stored unrefrigerated for up to 14 days at a temperature up to 30°C.

AJOVY must be discarded if not used within 14 days of removal from refrigeration.

Keep the pre-filled syringe(s) in the outer carton in order to protect from light.

Do not store AJOVY in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

Disposal

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

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

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.

Never put the used syringes 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.

Product description

What it looks like

AJOVY is a solution for injection in a pre-filled syringe with a fixed injection needle in a blister.

AJOVY is a clear, colourless to slightly yellow solution.

Each prefilled syringe contains 1.5 mL solution.

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

Ingredients

Each prefilled syringe of AJOVY contains 225 mg of fremanezumab as the active ingredient in 1.5 mL of solution (150 mg/mL).

Other ingredients are:

- 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.

Sponsor

AJOVY is supplied in Australia by:

Teva Pharma Australia Pty Ltd

37 Epping Rd

Macquarie Park, NSW, 2113

Toll Free Number: 1800 288 382

AUST R: 308630

This leaflet was prepared in September 2019.