

Package leaflet: Information for the patient

AJOVY® 225 mg solution for injection in pre-filled syringe fremanezumab

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What AJOVY is and what it is used for
2. What you need to know before you use AJOVY
3. How to use AJOVY
4. Possible side effects
5. How to store AJOVY
6. Contents of the pack and other information

1. What AJOVY is and what it is used for

What AJOVY is

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

How AJOVY works

A substance in the body called calcitonin gene-related peptide (CGRP) plays an important role in migraine. Fremanezumab attaches to CGRP and prevents it from working. This reduction in CGRP's activity reduces migraine attacks.

What AJOVY is used for

AJOVY is used to prevent migraine in adults who have at least 4 migraine days per month.

What are the benefits of using AJOVY

AJOVY reduces the frequency of migraine attacks and days with headache. This medicine also decreases the disability associated with migraine and it reduces the need for medicines used to treat migraine attacks.

2. What you need to know before you use AJOVY

Do not use AJOVY

Do not use this medicine if you are allergic to fremanezumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse immediately if you get any signs of a serious allergic reaction, e.g. trouble breathing, swelling of the lips and tongue, or severe rash, after injecting AJOVY. These reactions can occur within 24 hours after using AJOVY but can sometimes be delayed.

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.

Children and adolescents

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

Other medicines and AJOVY

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It is preferable to avoid the use of AJOVY during pregnancy as the effects of this medicine in pregnant women are not known.

If you are breast-feeding or are planning to breast-feed, talk to your doctor or pharmacist before using this medicine. You and your doctor should decide if you will use AJOVY while breast-feeding.

Driving and using machines

This medicine is not expected to have any effect on your ability to drive or use machines.

AJOVY contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially “sodium-free”.

3. How to use AJOVY

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

AJOVY is given by injection under your skin (subcutaneous injection). Your doctor or nurse will explain to you or your caregiver how to give the injection. Do not inject AJOVY until you or your caregiver have been trained by your doctor or nurse.

Read the “Instructions for Use” for the pre-filled syringe carefully before using AJOVY.

How much and when to inject

Your doctor will discuss and decide with you the most appropriate dosing schedule. There are two alternative recommended dosing options:

- one injection (225 mg) once a month (monthly dosing) or
- three injections (675 mg) every 3 months (quarterly dosing)

If your dose is 675 mg, inject the three injections one after another, each in a different place.

Use a reminder method such as notes in a calendar or diary to help you remember your next dose so that you do not miss a dose or have a dose too soon after the last one.

If you use more AJOVY than you should

If you have used more AJOVY than you should, tell your doctor.

If you forget or miss 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 when to inject AJOVY, talk to your doctor, pharmacist or nurse.

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

4. Possible side effects

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

The following side effects can occur:

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

Pain, hardening or redness at the injection site

Common (may affect up to 1 in 10 people)

Itching at the injection site

Uncommon (may affect up to 1 in 100 people)

Rash at the injection site

Allergic reactions such as rash, swelling or hives (see section 2)

Rare (may affect up to 1 in 1000 people)

Serious allergic reactions (signs may include trouble breathing, swelling of the lips, tongue or severe rash) (see section 2. “Warnings and precautions”).

Reporting of side effects

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

5. How to store AJOVY

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 syringe label and on the outer carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the pre-filled syringe in the outer carton to protect the medicine from light.

This medicine may be removed from the refrigerator and stored at a temperature up to 30 °C for a maximum period of up to 7 days. The medicine must be discarded if it has been out of the refrigerator for longer than 7 days. Once stored at room temperature, do not place back in the refrigerator.

Do not use this medicine if you notice that the outer carton has been tampered with, the syringe is damaged, or the medicine is cloudy, discoloured, or contains particles.

The syringe is for single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What AJOVY contains

- The active substance is fremanezumab.
Each pre-filled syringe contains 225 mg of fremanezumab.
- The other ingredients (excipients) are L-histidine, L-histidine hydrochloride monohydrate, sucrose, disodium ethylenediaminetetraacetic acid (EDTA) dihydrate, polysorbate 80 and water for injections.

What AJOVY looks like and contents of the pack

AJOVY is a solution for injection (injection) in a pre-filled syringe with a fixed injection needle in a blister. AJOVY is a clear, colourless to slightly yellow solution. Each pre-filled syringe contains 1.5 mL solution.

AJOVY is available in packs containing 1 or 3 pre-filled syringes. Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Merckle GmbH, Graf-Arco-Str. 3, 89079 Ulm, Germany

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Instructions for Use

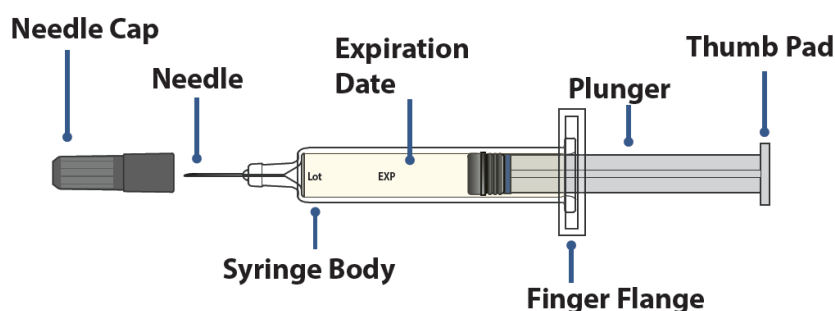
AJOVY® 225 mg solution for injection in pre-filled syringe fremanezumab

Before you use the AJOVY pre-filled syringe, read and carefully follow the step-by-step instructions.

Important information:

- The AJOVY pre-filled syringe is for single use only.
- Each AJOVY pre-filled syringe contains 225 mg of fremanezumab. Depending on your dose you will need to use 1 pre-filled syringe or 3 pre-filled syringes.
- AJOVY is injected under your skin (subcutaneous injection). You should not inject yourself until you have been trained by your doctor or nurse.
- Carefully read the AJOVY package leaflet to learn more about your medicine.
- **Do not** pull back on the plunger at any time as this can break the pre-filled syringe.
- **Do not** shake the pre-filled syringe.
- **Put the carton back in the refrigerator immediately**, if you have any unused pre-filled syringes in the carton.

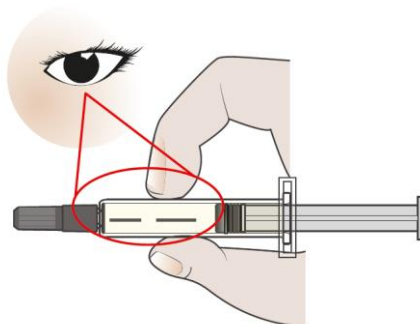
Parts of the AJOVY pre-filled syringe



Step 1: Getting ready for an injection

- Gather the following supplies for your injection:**
 - 1 or 3 AJOVY pre-filled syringes to enable 1 or 3 injections depending on your dose
 - 1 alcohol swab per injection
 - 1 gauze pad or cotton ball per injection
 - 1 sharps disposal or puncture-resistant container
- Place the supplies you have gathered on a clean, flat surface.**
- 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** remove needle cap.
- Wash your hands** with soap and water and dry well with a clean towel.
- Inspect your AJOVY pre-filled syringe.**
 - Check the syringe label. Make sure the name AJOVY appears on the label.

- Check that the medicine inside the syringe looks clear and is colourless to slightly yellow.
- You may see small air bubbles in the pre-filled syringe. This is normal.
- **Do not** use the pre-filled syringe if you see any of the following:
 - The syringe looks damaged.
 - The expiration date has passed or the pre-filled syringe has been out of the refrigerator for longer than 7 days.
 - The medicine is cloudy, discoloured, or contains particles.



f) Choose your injection area.

- **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.

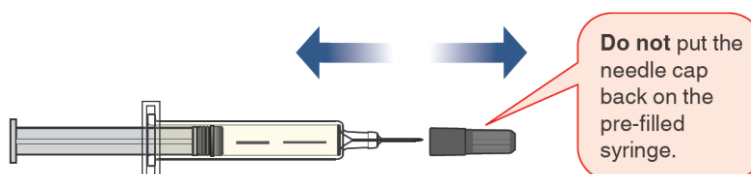


g) Clean your injection area.

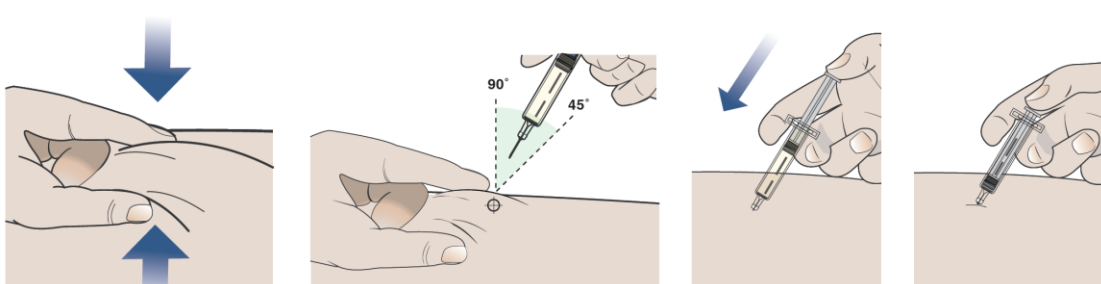
- Clean the chosen injection area using a new alcohol swab.
- Wait 10 seconds to allow the skin to dry before injecting.
- **Do not** inject AJOVY into an area that is tender, red, hot, bruised, hardened, tattooed or that has scars or stretch marks.

Step 2: How to inject

- a) Only when you are ready to inject, pull the needle cap straight off and throw it away.**
- **Do not** put the needle cap back on the pre-filled syringe, to avoid injury and infection.
 - **Do not** touch the needle.



b) Inject by following the 4 steps below.

1. Gently pinch up at least 2.5 cm of the skin that you have cleaned.	2. Insert the needle into the pinched skin at a 45° to 90° angle.	3. Slowly push the plunger in.	4. Push the plunger all the way down as far as it will go to inject all of the medicine.
			

c) Remove the needle from your skin.

- After you have injected all of the medicine, pull the needle straight out.
- **Do not** put the cap back on the needle at any time to avoid injury and infection.



d) Apply pressure at the injection site.

- Use a clean, dry cotton ball, or gauze to gently press on the injection site for a few seconds.
- **Do not** rub the injection site or re-use the pre-filled syringe.

Step 3: Disposal of the pre-filled syringe

a) Dispose of your pre-filled syringe right away.

- Put your used pre-filled syringes (with the needle still attached) in a sharps disposal container right away after use.
- **Do not** throw away (dispose of) loose needles, syringes, or pre-filled syringes with your household waste.
- **Do not** recycle used sharps disposal container.

b) Ask your doctor, pharmacist or nurse how to throw away the container.

If your dose is 675 mg, repeat steps 1 e) to 3 a) with the second and third pre-filled syringe to inject the full dose.