

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

AJOVY

Solution for subcutaneous injection
in pre-filled pen

Composition

Each pen contains:
fremanezumab 225 mg/1.5 ml

For information about inactive ingredients and allergens see section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

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

Therapeutic group: specific human monoclonal antibody to calcitonin gene-related peptide.

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

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.

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. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient fremanezumab or to any of the other ingredients of this medicine (see section 6 'Additional information').

Special warnings about using this medicine

Talk to your doctor, pharmacist or nurse immediately if you get any symptoms of an allergic reaction, for example trouble breathing, swelling of the lips or tongue, or severe rash, after injecting AJOVY. These reactions can occur within 24 hours from the start of treatment with the medicine, but can sometimes appear later.

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 intended for children and adolescents under 18 years old because it has not been studied in this age group.

Other medicines and AJOVY

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breastfeeding

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 breastfeeding or are planning to breastfeed, talk to your doctor or pharmacist before using this medicine. You and your doctor will have to decide if you will use AJOVY while breastfeeding.

Driving and using machines

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

Important information about some of this medicine's ingredients

This medicine contains less than 23 mg of sodium per pen and is therefore considered sodium-free.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

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 pen 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 (3-monthly dosing)

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

Do not exceed the recommended dose.

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 injected more AJOVY than you should, tell your doctor.

If you forget or miss an AJOVY injection

If you have missed a dose of AJOVY, inject your missed dose as soon as you can. Do not inject a double dose to make up for a forgotten dose. If you are not sure when to inject your next dose, talk to your doctor, pharmacist or nurse.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using AJOVY may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following side effects can occur:

Very common side effects (may affect more than 1 in 10 people)
Pain, hardening or redness at the injection site.

Common side effects (may affect up to 1 in 10 people)
Itching at the injection site.

Uncommon side effects (may affect up to 1 in 100 people)
Rash at the injection site.
Allergic reactions such as rash, swelling or hives (skin disorder) (see section 2).

Rare side effects (may affect up to 1 in 1,000 people)
Serious allergic reactions (signs may include trouble breathing, swelling of the lips, tongue or severe rash) (see section 2 'Special warnings about using this medicine').

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store in a refrigerator (2°C – 8°C). Do not freeze.**
- Keep the pre-filled pen in the original package to protect the medicine from light.**
- This medicine may be removed from the refrigerator and stored at a temperature below 25°C for a maximum period of up to 24 hours. Discard this medicine if it has been out of the refrigerator for longer than 24 hours.**
- Do not expose to direct sunlight or extreme heat.**
- Do not shake.
- Do not use this medicine if you notice that the outer carton is damaged, the pen is damaged, or the medicine is cloudy, discolored, or contains particles.
- The pen is for single use only.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Sucrose, L-histidine hydrochloride monohydrate, L-histidine, polysorbate 80, disodium ethylenediaminetetraacetic acid (EDTA) dihydrate, and water for injections.

What the medicine looks like and contents of the pack:

A clear, colorless to slightly yellow solution in a pre-filled pen for single use.
Each pre-filled pen contains 1.5 ml solution for injection.
Each pack contains 1 or 3 pre-filled pens in a carton package.
Not all pack sizes may be marketed.

Registration holder and manufacturer's name and address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

The leaflet was revised in January 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 162.86.35836

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DOR-Ajo-PEN-PIL-0322-05

AJOVY
solution for injection
in pre-filled pen



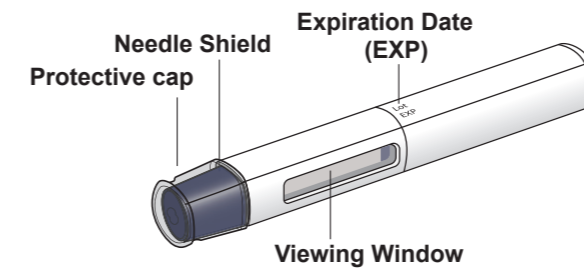
Instructions for use
AJOVY 225 mg solution for injection in pre-filled pen
fremanezumab

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

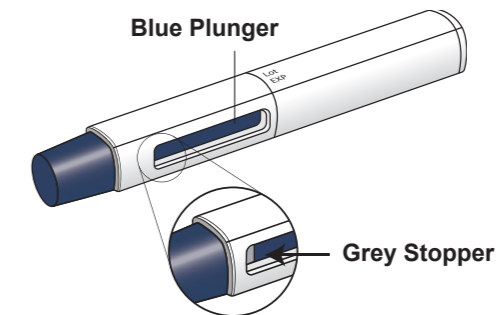
Important information:

- The AJOVY pre-filled pen is for single use only.
- Each AJOVY pre-filled pen contains 225 mg of fremanezumab. Depending on your dose you will need to use 1 pre-filled pen or 3 pre-filled pens.
- AJOVY is injected under your skin (subcutaneous injection). Do 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 shake** the pre-filled pen.
- If you have any unused pre-filled pens left in the outer package, **put them back in the refrigerator immediately.**

Parts of the AJOVY pre-filled pen (before use):



AJOVY pre-filled pen (after use):



- The blue plunger moves down the viewing window during the injection. The blue plunger fills the window when the injection is complete (note: when the blue plunger has filled the entire viewing window you will still be able to see the grey stopper).
- When injecting AJOVY, hold the pre-filled pen so that your hand does not cover the viewing window.

Step 1: Getting ready for an injection

a. Gather the following supplies for your injection.

- 1 or 3 AJOVY pre-filled pens to enable 1 or 3 injections depending on your dose.
- 1 alcohol swab per injection.
- 1 gauze pad or cotton ball per injection.
- sharps disposal or puncture-resistant container.

b. Place the supplies you have gathered on a clean, flat surface.

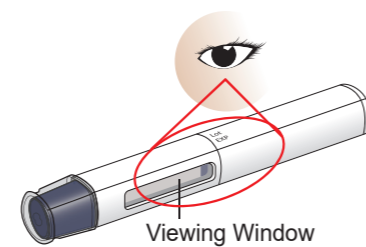
c. Wait for 30 minutes to let AJOVY reach room temperature (below 30°C) to reduce discomfort during injection.

- **Do not** leave the pre-filled pen in direct sunlight.
- **Do not** warm up the pre-filled pen using a microwave or any other heat source.

d. Wash your hands with soap and water and dry well with a clean towel.

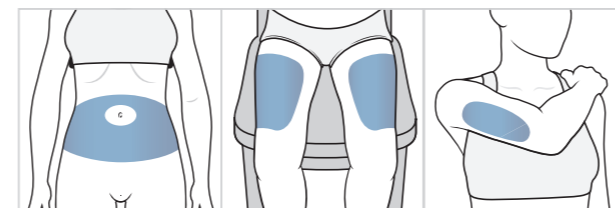
e. Inspect your AJOVY pre-filled pen.

- Check the pen label. Make sure the name AJOVY appears on the label.
- Check that the medicine inside the pen's viewing window looks clear and is colorless to slightly yellow.
- You may see small air bubbles in the pre-filled pen. This is normal.
- **Do not use** the pre-filled pen if you see any of the following:
 - The pen looks damaged.
 - The expiry date has passed, or if the pre-filled pen was left outside of the refrigerator for more than 24 hours.
 - The medicine is cloudy, discolored, 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, at least 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.



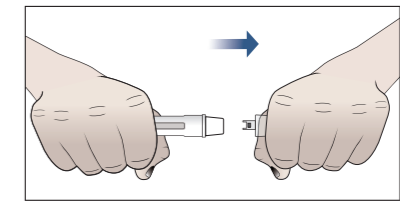
g. Clean your injection area.

- 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

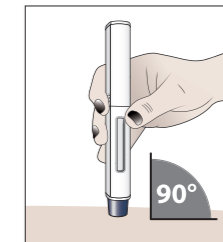
a. Remove the protective cap and do not replace it.

- Pull the protective cap straight off. **Do not** twist.
- **Do not** put the protective cap back on the pre-filled pen, to avoid injury and infection.
- **Do not** touch the needle shield area.



b. Inject by following the steps below

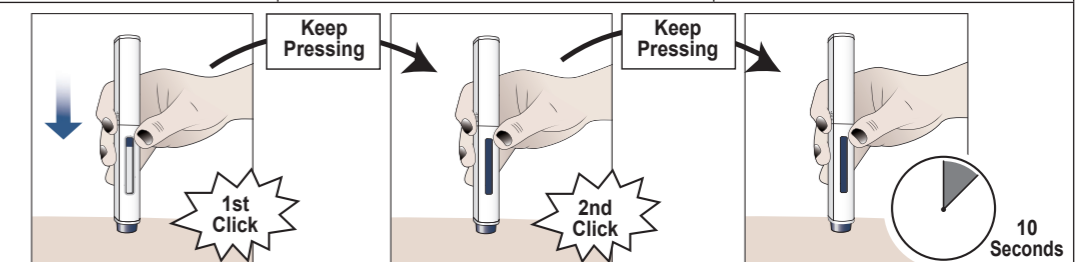
- Place the pre-filled pen at a 90° angle against your skin at the injection site.
- Press down on the pre-filled pen and keep pressed down against the skin for about 30 seconds. **Do not** remove pressure until the 3 steps below are complete:



1. You hear the first "click" (this signals the start of the injection and the blue plunger starts to move).

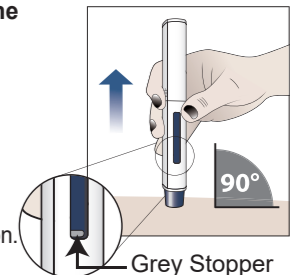
2. You hear a second "click" (about 15 seconds after the first "click"; the plunger moves towards the bottom of the viewing window as the medicine is being injected).

3. You wait another 10 seconds (to make sure that all of the medicine has been injected).



c. Check that the blue plunger has filled the viewing window and remove the pen from your skin.

- After you have injected all of the medicine, i.e. the blue plunger has filled the viewing window and you are able to see the grey stopper, remove the pen from your skin by lifting it straight up and immediately discard it into the sharps disposal container (see step 3).
- As the pre-filled pen is lifted from the skin, the needle shield returns to its original position and locks into place, covering the needle.
- **Do not** put the protective cap back on the pen 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 pen.

Step 3: Discard the pre-filled pen.

a. Discard the pre-filled pen immediately.

- Put your used pens into a sharps disposal container right away after use.
- **Do not** throw away (dispose of) pre-filled pens with your household waste.
- **Do not** recycle your used sharps disposal container.

b. Ask your doctor, pharmacist or nurse how to throw away the container with the used pens.

If your dose is 675 mg, repeat steps 1 (e) to 3 (a) with the second and third pens to inject the full dose you were prescribed.