# A Guide to Talking with Your Doctor about AJOVY

This Discussion Guide can help you prepare for your next appointment with your doctor. Print it out to work through with your doctor to determine if AJOVY is right for you.

1. On average, how many migraine days do you have each month?

   0-4  
   4-14  
   15+  

2. How often do you take medication when you feel a migraine attack coming?

   Never  
   Rarely  
   Frequently  
   Always  

3. List the symptoms you experience when you have a migraine attack.

4. How does migraine affect your daily life?

   TIP: Being as descriptive as possible may help your healthcare provider come up with a more thorough treatment plan.

   TIP: Tracking your migraine is critical because it may help your healthcare provider better understand the impact migraine has on your life.

   TIP: Include everything migraine stops you from doing—from not being able to sit through a movie, or focus on work, to missing outings and events.

5. How many times a month do you typically miss out on things because migraine got in the way?

   Only a few (0-2 times)  
   Several (3-7 times)  
   Many (8-12 times)  
   Too often (over 12 times)  

Download the migraine tracker at [AJOVY.com/Considering-AJOVY](http://AJOVY.com/Considering-AJOVY).

## Approved Use

AJOVY is a prescription medicine used for the preventive treatment of migraine in adults.

## Important Safety Information (continued on following page)

Do not use AJOVY if you are allergic to AJOVY or any of the ingredients in AJOVY.

AJOVY may cause allergic reactions, including itching, rash, and hives that can happen within hours and up to 1 month after receiving AJOVY. Call your healthcare provider or get emergency medical help right away if you have any symptoms of an allergic reaction: swelling of your face, mouth, tongue, throat, or if you have trouble breathing. Talk to your doctor about stopping AJOVY if you have an allergic reaction.

Please read the Patient Information Leaflet within the Full Prescribing Information on the accompanying pages.
A GUIDE TO TALKING WITH YOUR DOCTOR ABOUT AJOVY (cont.)

6. Rate the intensity of your migraine episodes over the last month.

TIP: Rate the intensity of your migraine episodes before you alter your surroundings and/or activities to lessen their impact, to avoid understating how migraine impacts your life.

1 2 3 4 5 6 7 8 9 10

7. Select the activities that might interfere with taking medication on a regular basis.

- Unpredictable schedule
- Active lifestyle
- Planning a pregnancy
- Other

8. What does your weekly routine look like? Select all that apply.

- Work
- Exercise
- Errands
- Kid activities
- Self-care

9. Keeping your current routine in mind, would you rather take medication 4 times a year or 12 times a year?*

- QUARTERLY 4 times per year
- MONTHLY 12 times per year

*Quarterly dosing is three 225 mg subcutaneous injections every 3 months. Monthly dosing is one 225 mg subcutaneous injection each month.

10. When it comes to possible side effects, which are you most concerned about? List them below.

11. Is paying for AJOVY something that concerns you?

- A lot
- Somewhat
- A little
- Not at all

IMPORTANT SAFETY INFORMATION (CONTINUED)

Tell your healthcare provider about all the medicines you take, and if you are pregnant, planning to become pregnant, or are breastfeeding.

Common side effects of AJOVY include injection site reactions.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of AJOVY. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA at 1-800-FDA-1088.
AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Reactions have included anaphylaxis and angioedema. (4)

RECENT MAJOR CHANGES
Dosage and Administration, Important Administration Instructions (2.2) 10/2020
Contraindications (4) 5/2020
Warnings and Precautions (5.3) 9/2021

INDICATIONS AND USAGE
AJOVY is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults. (1)

DOSAGE AND ADMINISTRATION
• For subcutaneous use only (2.1, 2.2)
• Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:
  - 225 mg monthly, or
  - 675 mg every 3 months (quarterly) (2.1)
• The 675 mg quarterly dosage is administered as three consecutive injections of 225 mg each. (2.1)

SAFETY INFORMATION
Hypersensitivity Reactions: If hypersensitivity occurs, consider discontinuing AJOVY and institute appropriate therapy. (5.1)

ADVERSE REACTIONS
The most common adverse reactions (≥5% and greater than placebo) were injection site reactions. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 9/2021

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
AJOVY is indicated for the preventive treatment of migraine in adults.

2 DOSAGE AND ADMINISTRATION
2.1 Recommended Dosage
Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:
• 225 mg monthly, or
• 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each.

When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of AJOVY is missed, administer as soon as possible. Thereafter, AJOVY can be scheduled from the date of the last dose.

2.2 Important Administration Instructions
AJOVY is for subcutaneous use only.
AJOVY may be administered by healthcare professionals, patients, and/or caregivers. Prior to use, provide proper training to patients and/or caregivers on the preparation and administration of AJOVY prefilled syringe, including aseptic technique (see Instructions for Use).

• Remove AJOVY from the refrigerator. Prior to use, allow AJOVY to sit at room temperature for 30 minutes protected from direct sunlight. Do not warm by using a heat source such as hot water or a microwave. Do not use AJOVY if it has been at room temperature for 7 days or longer (see How Supplied/Storage and Handling (16.2)).
• Follow aseptic injection technique every time AJOVY is administered.
• Inspect AJOVY for particles or discoloration prior to administration (see Dosage Forms and Strengths (3)). Do not use if the solution is cloudy, discolored, or contains particles.
• Administer AJOVY by subcutaneous injection into areas of the abdomen, thigh, or upper arm that are not tender, bruised, red, or indurated. For multiple injections, you may use the same body site, but not the exact location of the previous injection.
• Do not co-administer AJOVY with other injectable drugs at the same injection site.

3 DOSAGE FORMS AND STRENGTHS
AJOVY is a sterile, clear to opalescent, colorless to slightly yellow solution, available as follows:
• Injection: 225 mg/1.5 mL single-dose prefilled autoinjector
• Injection: 225 mg/1.5 mL single-dose prefilled syringe

4 CONTRAINDICATIONS
AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab-vfrm or to any of the excipients. Reactions have included anaphylaxis and angioedema (see Warnings and Precautions (5.1)).
6.2 Immunogenicity
As with all therapeutic proteins, there is a potential for immunogenicity. The detection of antibody formation is highly dependent on sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, sample medium, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to fremanezumab-vfrm in the studies described below with the incidence of antibodies in other studies to other products may be misleading. Clinical immunogenicity of AJOVY was monitored by analyzing anti-drug antibodies (ADA) and neutralizing antibodies in drug-treated patients. The data reflect the percentage of patients whose post-treatment serum samples were positive for antibodies to AJOVY in specific assays. In 3-month placebo-controlled studies, treatment-emergent ADA responses were observed in 6 out of 170 (0.4%) AJOVY-treated patients. One of the 6 patients developed anti-AJOVY neutralizing antibodies at Day 84. In the ongoing long-term open-label study, ADA were detected in 16% of patients (30 out of 1868). Out of 30 ADA-positive patients, 17 had a neutralizing activity in their post-dose serum samples. None of these data do not demonstrate an impact of anti-fremanezumab-vfrm antibody development on the efficacy or safety of AJOVY in these patients, the available data are too limited to make definitive conclusions.

6.3 Postmarketing Experience
The following adverse reactions have been identified during postapproval use of AJOVY. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Immune System Disorders - Anaphylactic reactions and angioedema [see Contraindications (4) and Warnings and Precautions (5.3)].

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy

8.1.1 Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AJOVY during pregnancy. Healthcare providers are encouraged to register pregnant patients, or pregnant women may enroll themselves in the registry by calling 1-833-927-2605 or visiting www.tevamigrainepregnancyregistry.com.

Risk Summary
There are no adequate data on the developmental risk associated with the use of AJOVY in pregnant women. AJOVY has a long half-life [see Clinical Pharmacology (12.3)]. This should be taken into consideration for women who are pregnant or plan to become pregnant while being treated with AJOVY. Administration of fremanezumab-vfrm to rats and rabbits during the period of organogenesis or to rats throughout pregnancy and lactation at doses resulting in plasma levels greater than those expected clinically did not result in adverse effects on development [see Animal Data]. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The estimated rate of major birth defects (2.2-2.9%) and miscarriage (17%) among deliveries to women with migraine are similar to rates reported in women without migraine.

Clinical Considerations

8.1.2 Disease-Associated Maternal and/or Embryofetal Risk
Published data have suggested that women with migraine may be at increased risk of preeclampsia and gestational hypertension during pregnancy. Data

Animal Data
When fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) was administered to male and female rats by weekly subcutaneous injection prior to and during mating and continuing in females throughout organogenesis, no adverse embryofetal effects were observed. The highest dose tested was associated with plasma exposures (AUC) approximately 2 times that in humans at a dose of 675 mg. Administration of fremanezumab-vfrm (0, 10, 50, or 100 mg/kg) weekly by subcutaneous injection to pregnant rabbits throughout the period of organogenesis produced no adverse effects on embryofetal development. The highest dose tested was associated with plasma AUC approximately 3 times that in humans (675 mg). Administration of fremanezumab-vfrm (0, 50, 100, or 200 mg/kg) weekly by subcutaneous injection to female rats throughout pregnancy and lactation resulted in no adverse effects on pre- and postnatal development. The highest dose tested was associated with plasma AUC approximately 2 times that in humans (675 mg).

8.2 Lactation
Risk Summary
There are no data on the presence of fremanezumab-vfrm in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for AJOVY and any potential adverse effects on the breastfed infant from AJOVY or from the underlying maternal condition.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use
Clinical studies of AJOVY did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

11 DESCRIPTION
Fremanezumab-vfrm is a fully humanized IgG2a/kappa monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. Fremanezumab-vfrm is produced by recombinant DNA technology in Chinese hamster (CHO) cells. The antibody consists of 1324 amino acids and has a molecular weight of approximately 148 kDa. AJOVY (fremanezumab-vfrm) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for subcutaneous injection, supplied in a single-dose 225 mg/1.5 mL prefilled autoinjector and a single-dose 225 mg/1.5 mL prefilled syringe.
Both monthly and quarterly dosing regimens of AJOVY demonstrated statistically significant improvements for efficacy endpoints compared to placebo over the 3-month period, as summarized in Table 2.

### Table 2: Efficacy Endpoints in Study 1

<table>
<thead>
<tr>
<th>Study 1</th>
<th>Efficacy Endpoint</th>
<th>AJOVY 225 mg Monthly (N=287)</th>
<th>AJOVY 675 mg Quarterly (N=288)</th>
<th>Placebo (N=290)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly migraine days (MMD)</td>
<td>Baseline migraine days</td>
<td>8.9</td>
<td>9.2</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>Change from baseline</td>
<td>-3.7</td>
<td>-3.4</td>
<td>-2.2</td>
</tr>
<tr>
<td></td>
<td>Difference from placebo</td>
<td>-1.5</td>
<td>-1.2</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>≥50% MDD responders</td>
<td>% responders</td>
<td>47.2%</td>
<td>44.4%</td>
<td>27.5%</td>
</tr>
<tr>
<td></td>
<td>Difference from placebo</td>
<td>19.8%</td>
<td>16.5%</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>Monthly acute headache medication days</td>
<td>Change from baseline</td>
<td>-3.0</td>
<td>-2.9</td>
<td>-1.6</td>
</tr>
<tr>
<td></td>
<td>Difference from placebo</td>
<td>-1.4</td>
<td>-1.3</td>
<td>-1.0</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Figure 1 displays the mean change from baseline in the average monthly number of migraine days in Study 1.

**Figure 1: Change from Baseline in Monthly Migraine Days in Study 1**

![Change from Baseline in Monthly Migraine Days in Study 1](image)

*LS (least-square) means and standard error of the mean are presented.

Figure 2 shows the distribution of change from baseline in mean monthly migraine days in bins of 2 days by treatment group in Study 1. A treatment benefit over placebo for both doses of AJOVY is seen across a range of changes from baseline in monthly migraine days.

**Figure 2: Distribution of Change from Baseline in Mean Monthly Migraine Days by Treatment Group in Study 1**

![Distribution of Change from Baseline in Mean Monthly Migraine Days by Treatment Group in Study 1](image)

Chronic Migraine

Study 2 (NCT 02621931) included adults with a history of chronic migraine (patients with ≥15 headache days per month). All patients were randomized (1:1:1) to receive subcutaneous injections of either AJOVY 675 mg starting dose followed by 225 mg monthly, 675 mg every 3 months (quarterly), or placebo monthly, over a 3-month treatment period. Patients were allowed to use acute headache treatments during the study. A subset of patients (21%) was allowed to use one additional concomitant, preventive medication.

The study excluded patients with a history of significant cardiovascular disease, vascular ischemia, or thrombotic events, such as cerebrovascular accident, transient ischemic attacks, deep vein thrombosis, or pulmonary embolism.

Figure 3 displays the distribution of change from baseline in monthly headache days of at least moderate severity in Study 2.

**Figure 3: Change from Baseline in Monthly Headache Days of At Least Moderate Severity in Study 2**

![Change from Baseline in Monthly Headache Days of At Least Moderate Severity in Study 2](image)

*LS (least-square) means and standard error of the mean are presented.

Figure 4 shows the distribution of change from baseline in monthly headache days of at least moderate severity at month 3 in bins of 3 days by treatment group. A treatment benefit over placebo for both dosing regimens of AJOVY is seen across a range of changes from baseline in headache days.

**Figure 4: Change from Baseline in Monthly Headache Days of At Least Moderate Severity in Study 2**

![Change from Baseline in Monthly Headache Days of At Least Moderate Severity in Study 2](image)

*LS (least-square) means and standard error of the mean are presented.

The primary efficacy endpoint was the mean change from baseline in the monthly average number of headache days of at least moderate severity during the 3-month treatment period. The secondary endpoints were the mean change from baseline in the monthly average number of migraine days during the 3-month treatment period, the proportion of patients reaching at least 50% reduction in the monthly average number of headache days of at least moderate severity during the 3-month treatment period, the mean change from baseline in the monthly average number of days of use of any acute headache medication during the 3-month treatment period, and the mean change from baseline in the number of headache days of at least moderate severity during the first month of treatment.

In Study 2, a total of 1130 patients (591 females, 139 males), ranging in age from 18 to 70 years, were randomized. A total of 1034 patients completed the 3-month double-blind phase.

Both monthly and quarterly dosing regimens of AJOVY treatment demonstrated statistically significant improvement for key efficacy outcomes compared to placebo, as summarized in Table 3.

### Table 3: Efficacy Endpoints in Study 2

<table>
<thead>
<tr>
<th>Study 2</th>
<th>Efficacy Endpoint</th>
<th>AJOVY 225 mg Monthly (N=375)</th>
<th>AJOVY 675 mg Quarterly (N=375)</th>
<th>Placebo (N=371)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline headache days of any severity</td>
<td>Change from baseline</td>
<td>-4.6</td>
<td>-4.3</td>
<td>-2.5</td>
</tr>
<tr>
<td></td>
<td>Difference from placebo</td>
<td>-2.1</td>
<td>-1.8</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>Baseline headache days of at least moderate severity</td>
<td>Change from baseline</td>
<td>-4.6</td>
<td>-4.6</td>
<td>-2.3</td>
</tr>
<tr>
<td></td>
<td>Difference from placebo</td>
<td>-4.6</td>
<td>-4.6</td>
<td>-2.3</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>-</td>
</tr>
<tr>
<td>Percentage of patients with ≥50% reduction in monthly average number of headache days of at least moderate severity during 4 weeks after 1st dose</td>
<td>Change from baseline</td>
<td>40.8%</td>
<td>37.8%</td>
<td>18.3%</td>
</tr>
<tr>
<td></td>
<td>Percentage of patients with ≥50% reduction in monthly average number of days of acute headache medication</td>
<td>-4.2</td>
<td>-3.7</td>
<td>-1.9</td>
</tr>
<tr>
<td></td>
<td>Change from baseline</td>
<td>-4.2</td>
<td>-3.7</td>
<td>-1.9</td>
</tr>
<tr>
<td></td>
<td>p-value</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*In Study 2, patients received a 675 mg starting dose.

*Used for chronic migraine diagnosis.

*Used for primary endpoint analysis.

AJOVY® (fremanezumab-vfrm) injection
AJOVY® (fremanezumab-vfrm) injection

What is AJOVY?
AJOVY is a prescription medicine used for the preventive treatment of migraine in adults. It is not known if AJOVY is safe and effective in children.

Who should not use AJOVY?
Do not use AJOVY if you are allergic to fremanezumab-vfrm or any of the ingredients in AJOVY. See the end of this leaflet for a complete list of the ingredients in AJOVY.

Before you use AJOVY, tell your healthcare provider if you:
• are pregnant or plan to become pregnant. It is not known if AJOVY will harm your unborn baby.

Pregnancy Registry: There is a registry for women who become pregnant during treatment with AJOVY. The purpose of this registry is to collect information about the safety of AJOVY during pregnancy. Contact the registry as soon as you learn that you are pregnant, or ask your doctor to contact the registry for you. You or your doctor can get information and enroll you in the registry by calling 1-833-927-2605 or visiting www.tevamigrainepregnancyregistry.com.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use AJOVY?
• See the detailed "Instructions for Use" for information on how to prepare and inject a dose of AJOVY.
• Use AJOVY exactly as your healthcare provider tells you to use it.
• AJOVY is given by injection under your skin (subcutaneously).

Your healthcare provider should show you or your caregiver how to prepare and inject your dose of AJOVY before you or your caregiver give your AJOVY the first time.

Your healthcare provider will tell you how much AJOVY to use and when to use it:
- Your healthcare provider will tell you if you should use AJOVY 225 mg one time every month or AJOVY 675 mg one time every 3 months.
- If your prescribed dose is AJOVY 675 mg every 3 months, you must use 3 separate autoinjectors or 3 separate syringes. You will give 3 separate injections one time every 3 months.
- If you are giving 3 injections of AJOVY for your prescribed dose, you may use the same injection area for all 3 injections, but not the same spot.
• Do not inject AJOVY in the same injection site that you inject other medicine.
• If you are switching from using AJOVY one time every month to one time every 3 months or if you are switching from using AJOVY one time every 3 months to one time every month, give the first dose of AJOVY on the day it was due to be given on your old schedule.
• If you miss a dose of AJOVY, take it as soon as possible. If you need to take the dose late, you will need to change your schedule: if you take 225 mg of AJOVY, inject your next dose 1 month after the late dose. If you take 675 mg of AJOVY, inject your next dose 3 months after the late dose. If you have questions about your schedule, ask your healthcare provider.

PATIENT COUNSELING INFORMATION
Advising the patient and/or caregiver to read the FDA-approved patient labeling (Patient Information and Instructions for Use).
Information on Preparation and Administration
Provide guidance to patients and caregivers on proper subcutaneous administration technique, including aseptic technique, and how to use the single-dose prefilled syringe (see Dosage and Administration (2.2)). Instruct patients and/or caregivers to read and follow the Instructions for Use each time they use AJOVY.

Instruct patients prescribed the regimen of 675 mg every 3 months to administer the dosage as three consecutive subcutaneous injections of 225 mg each (see Dosage and Administration (2.1)).

Hypersensitivity Reactions
Inform patients about the signs and symptoms of hypersensitivity reactions and that these reactions can occur up to 1 month after administration. Advise patients to contact their healthcare provider immediately if signs or symptoms of hypersensitivity reactions occur (see Warnings and Precautions (5.1)).

Pregnancy
Advise women that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to AJOVY during pregnancy (see Use in Specific Populations (8.1)).

Manufactured by:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454
US License No. 2016

AJOVY® (fremanezumab-vfrm), its use, or its process of manufacture, may be protected by one or more United States patents, including US 8,007,794, US 8,586,045 and US 9,896,502.

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AJO-009

continued
What are the possible side effects of AJOVY?

AJOVY may cause serious side effects, including:

- Allergic reactions. Allergic reactions, including itching, rash, and hives, can happen within hours and up to 1 month after receiving AJOVY. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms of an allergic reaction:
  - swelling of your face, mouth, tongue, or throat
  - trouble breathing

The most common side effects of AJOVY include:

- injection site reactions
- burning

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AJOVY. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AJOVY?

- Store AJOVY in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep AJOVY in the carton it comes in to protect from light.
- If needed, AJOVY may be stored at room temperature up to 86°F (30°C) in the carton it comes in for up to 7 days. Do not use AJOVY if it has been out of the refrigerator for 7 days or longer. Throw away (dispose of) AJOVY in a sharps disposal or puncture-resistant container if it has been out of the refrigerator for 7 days or longer. Once stored at room temperature, do not place back in the refrigerator.
- Do not freeze. If AJOVY freezes, throw it away in a sharps disposal container.
- Keep AJOVY out of extreme heat and direct sunlight.
- Do not shake AJOVY.

Keep AJOVY prefilled autoinjector and AJOVY prefilled syringe out of the reach of small children.

General information about the safe and effective use of AJOVY.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use AJOVY for a condition for which it was not prescribed. Do not give AJOVY to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AJOVY that is written for health professionals.

What are the ingredients in AJOVY?

Active ingredient: fremanezumab-vfrm

Inactive ingredients: disodium ethylenediaminetetraacetic acid dihydrate (EDTA), L-histidine, L-histidine hydrochloride monohydrate, polysorbate-80, sucrose, and Water for Injection.

AJOVY prefilled syringe and prefilled autoinjector are not made with natural rubber latex.

Manufactured by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454
US License No. 2016
AJOPL-005

For more information, go to www.AJOVY.com or call 1-888-483-8279.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 9/2021
AJOVY® (fremanezumab-vfrm) injection

Read this before you inject.

Step 1. Check the dose your healthcare provider has prescribed.
AJOVY comes as a single-dose (one time) prefilled autoinjector. Your healthcare provider will prescribe the dose that is best for you.
- If your healthcare provider has prescribed 225 mg of AJOVY each month for you, give 1 injection each month, using a 225 mg prefilled AJOVY autoinjector.
- If your healthcare provider has prescribed 675 mg of AJOVY every 3 months for you, give 3 separate injections, one after another, using a different 225 mg prefilled AJOVY autoinjector for each injection. Give these injections 1 time every 3 months.

Before you inject, always check the label of your single-dose prefilled autoinjector to make sure you have the correct medicine and the correct dose of AJOVY. If you are not sure of your dose, ask your healthcare provider.

How do I inject AJOVY?

Step 2. Remove the prefilled autoinjector from the carton.
- You may need to use more than 1 prefilled autoinjector depending on your prescribed dose.
- Remove the autoinjector from the carton (see Figure C).
- Do not shake the prefilled autoinjector at any time, as this could affect the way the medicine works.

Important: If there are any unused autoinjectors left in the carton, put the carton and unused autoinjectors back in the refrigerator.

Step 3. Gather the supplies you will need to inject AJOVY.
- Gather the following supplies (see Figure D) and the number of AJOVY 225 mg prefilled autoinjectors you will need to give your prescribed dose:
  - If your dose is 225 mg, you will need 1 AJOVY 225 mg prefilled autoinjector.
  - If your dose is 675 mg, you will need 3 AJOVY 225 mg prefilled autoinjectors.
- Alcohol swabs (not supplied).
- Gauze pads or cotton balls (not supplied).
- Sharps disposal or puncture-resistant container (not supplied).

Step 4. Let AJOVY reach room temperature.
- Place the supplies you have gathered on a clean, flat surface.
- Wait for 30 minutes to allow the medicine to reach room temperature.
- Do not leave the prefilled autoinjector in direct sunlight.
- Do not warm up the AJOVY prefilled autoinjector using a heat source such as hot water or a microwave.

Step 5. Wash your hands.
- Wash your hands with soap and water and dry well with a clean towel. Be careful not to touch your face or hair after washing your hands.

Step 6. Look closely at your AJOVY prefilled autoinjector.
Note: You may see air bubbles in the prefilled autoinjector. This is normal. Do not remove the air bubbles from the prefilled autoinjector before giving your injection.

Injecting AJOVY with these air bubbles will not harm you.

- Check that the liquid medicine in the prefilled autoinjector viewing window is clear and colorless to slightly yellow before you give your injection. (See Figure E). If the liquid has any particles in it, or is discolored, cloudy, or frozen, do not use the prefilled autoinjector. Call your healthcare provider or pharmacist.
- Do not use the prefilled autoinjector if it has any visible damage, such as cracks or leaks. See disposal instructions in Step 12.

Step 7. Choose your injection area.
- Choose an injection area from the following areas (see Figure F):
  - your stomach area (abdomen), avoid about 2 inches around the belly button.
  - the front of your thighs, an area that is at least 2 inches above the knee and 2 inches below the groin.
  - the back of your upper arms, in the fleshy area of the upper back portion.

Note: There are some injection areas on your body that are hard to reach (like the back of your arm). You may need help from someone who has been instructed on how to give your injection if you cannot reach certain injection areas.

Step 8. Clean your injection area.
- Clean the chosen injection area using a new alcohol swab. Let your skin dry.
- Do not inject AJOVY into an area that is tender, red, bruised, callused, tattooed, hard, or that has scars or stretch marks.
- Do not inject AJOVY in the same injection site that you inject other medicine.
- If you want to use the same injection area for the 3 separate injections needed for the 675 mg dose, make sure the second and third injections are not at the same spot you used for the other injections.

Step 9. Remove protective cap and do not replace.
- Pick up the prefilled autoinjector in 1 hand.
- Hold the prefilled autoinjector as shown in Figure G and pull the protective cap straight off with your other hand. Do not twist.
Step 10. Give your injection.

- 10.1 Place the prefilled autoinjector at a 90 degree angle against your skin at the injection site you have cleaned (see Figure H).

- 10.2 Press down on the prefilled autoinjector and keep holding it 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 means the injection has started and the blue plunger starts to move).

2. You 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.)

3. You wait another 10 seconds. (to make sure all the medicine is injected).

- 10.3 Check that the blue plunger has filled the viewing window and remove the autoinjector from the skin by lifting the prefilled autoinjector straight up (see Figure I).

  Note: When the blue plunger has filled the viewing window you will be able to see the gray stopper.

  As the prefilled autoinjector is lifted from the skin, the needle shield returns to the original (before use) position and locks into place. Do not try to put the protective cap back on the used prefilled autoinjector as it is no longer needed. Do not try to re-use the prefilled autoinjector.

Step 11. Apply pressure to the injection site.

- Use a clean, dry cotton ball, or gauze pad to gently press on the injection site for a few seconds.

- Do not rub the injection site.

- Do not re-use the prefilled autoinjector.

Step 12. Dispose of your prefilled autoinjector right away.

- Put your used prefilled autoinjectors in a FDA-cleared sharps disposal container right away after use.

- Do not throw away (dispose of) prefilled autoinjectors in your household trash. Do not recycle your used sharps disposal container.

- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used autoinjectors. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal

- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Injection Complete

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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North Wales, PA 19454
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Instructions for Use
AJOVY® (a-JO-vee)
(fremanezumab-vfrm) injection
prefilled syringe, for subcutaneous use

For subcutaneous injection only.
Read and follow the Instructions for Use for your AJOVY prefilled syringe before you start using it and each time you get a refill.

Important:
- AJOVY prefilled syringe is for single-time (one-time) use only. Put AJOVY in a FDA-cleared sharps disposal or puncture-resistant container right away after use. Do not throw away (dispose of) your used sharps disposal container in your household trash.
- Before injecting, let AJOVY sit at room temperature for 30 minutes.
- Keep AJOVY prefilled syringe out of the reach of small children.
- After you remove the needle cap from AJOVY, to prevent infection, do not touch the needle.
- Do not pull back on the plunger at any time, as this can break the prefilled syringe.
- Do not inject AJOVY in your veins (intravenously).
- Do not re-use your AJOVY prefilled syringe, as this could cause injury or infection.
- Do not share your AJOVY prefilled syringe with another person. You may give another person an infection or get an infection from them.
You may give AJOVY® (fremanezumab-vfrm) injection yourself. If you feel uncomfortable, you should not get your first dose of AJOVY until you or your caregiver receive training from a healthcare provider on the right way to use AJOVY.

**Storage Conditions:**
- Store AJOVY® (fremanezumab-vfrm) injection in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep AJOVY® in the carton in protect from light.
- If needed, AJOVY® may be stored at room temperature up to 86°F (30°C) in the carton it comes in for up to 7 days. Do not use AJOVY® if it has been out of the refrigerator for 7 days or longer. Throw away (dispose of) AJOVY® in a sharps disposal or puncture-resistant container if it has been out of the refrigerator for 7 days or longer. Once stored at room temperature, do not place back in the refrigerator.
- Do not freeze. If AJOVY® freezes, throw it away in a sharps disposal container.
- Keep AJOVY® out of extreme heat and direct sunlight.
- Do not shake AJOVY®.

**AJOVY prefilled syringe (Before use).** See Figure A.

**AJOVY prefilled syringe (After use).** See Figure B.

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**Step 1. Check the dose your healthcare provider has prescribed.**
AJOVY comes as a single-dose (one time) prefilled syringe. Your healthcare provider will prescribe the dose that is best for you.
- If your healthcare provider has prescribed 225 mg of AJOVY® each month for you, give 1 injection each month using a 225 mg prefilled AJOVY® syringe.
- If your healthcare provider has prescribed 675 mg of AJOVY® every 3 months for you, give 3 separate injections, one after another, using a different 225 mg prefilled AJOVY® syringe for each injection. Give these injections 1 time every 3 months.

Before you inject, always check the label of your single-dose prefilled syringe to make sure you have the correct medicine and the correct dose of AJOVY®. If you are not sure of your dose, ask your healthcare provider.

**How do I inject AJOVY®?**

**Step 2. Remove the prefilled syringe from the carton.**
- You may need to use more than 1 prefilled syringe depending on your prescribed dose.
- **Hold** the prefilled syringe (as shown in Figure C).
- **Remove** the syringe from the carton.
- Do not shake the prefilled syringe at any time, as this could affect the way the medicine works.

**Step 3. Gather the supplies you will need to inject AJOVY®.**
- **Gather** the following supplies (see Figure D) and the number of AJOVY® prefilled syringes you will need to give your prescribed dose:
  - If your dose is 225 mg, you will need 1 AJOVY® 225 mg prefilled syringe.
  - If your dose is 675 mg, you will need 3 AJOVY® 225 mg prefilled syringes.
  - **alcohol swabs** (not supplied).
  - **gauze pads or cotton balls** (not supplied).
  - **sharps disposal or puncture-resistant container** (not supplied).

**Step 4. Let AJOVY® reach room temperature.**
- Place the supplies you have gathered on a clean, flat surface.
- Wait for 30 minutes to allow the medicine to reach room temperature.
- Do not leave the prefilled syringe in direct sunlight.
- Do not warm up the AJOVY® prefilled syringe using a heat source such as hot water or a microwave.

**Step 5. Wash your hands.**
- Wash your hands with soap and water and dry well with a clean towel. Be careful not to touch your face or hair after washing your hands.

**Step 6. Look closely at your AJOVY prefilled syringe.**
**Note:** You may see air bubbles in the prefilled syringe. This is normal. Do not remove the air bubbles from the prefilled syringe before giving your injection. Injecting AJOVY® with these air bubbles will not harm you.

**Check that the liquid medicine in the prefilled syringe is clear and colorless to slightly yellow before you give your injection** (see Figure E). If the liquid has any particles in it, or is discolored, cloudy, or frozen, do not use the prefilled syringe. Call your healthcare provider or pharmacist.

**Check that AJOVY® appears on the prefilled syringe.**
**Do not** use the prefilled syringe if it has any visible damage, such as cracks or leaks. See disposal instructions in Step 12.

**Check the expiration date (EXP) printed on the prefilled syringe label.**
**Do not** use the prefilled syringe if the expiration date (EXP) has passed.
Step 7. Choose your injection area.
- Choose an injection area from the following areas (see Figure F):
  - your stomach area (abdomen), avoid about 2 inches around the belly button.
  - the front of your thighs, an area that is at least 2 inches above the knee and 2 inches below the groin.
  - the back of your upper arms, in the fleshy area of the upper back portion.

Note: There are some injection areas on your body that are hard to reach (like the back of your arm). You may need help from someone who has been instructed on how to give your injection if you cannot reach certain injection areas.

Step 8. Clean your injection area.
- Clean the chosen injection area using a new alcohol swab. Let your skin dry.
- Do not inject AJOVY into an area that is tender, red, bruised, callused, tattooed, hard, or that has scars or stretch marks.
- Do not inject AJOVY in the same injection site that you inject other medicine.
- If you want to use the same injection area for the 3 separate injections needed for the 675 mg dose, make sure the second and third injections are not at the same spot you used for the other injections.

Step 9. Remove needle cap and do not replace.
- Pick up the body of the prefilled syringe with 1 hand.
- Pull the needle cap straight off with your other hand (see Figure G).
- Do not twist.
- Throw away the needle cap right away.
- Do not put the needle cap back on the prefilled syringe, to avoid injury and infection.

Step 10. Give your injection following the 4 steps below.

1. Use your free hand to gently pinch up at least 1 inch of the skin that you have cleaned.
2. Insert the needle into the pinched skin at a 45 to 90 degree angle.
3. When the needle is all the way into your skin, use your thumb to push the plunger.
4. Push the plunger slowly all the way down as far as it will go to inject all of the medicine.

Step 11. Remove the needle from your skin.
- After you have injected all of the medicine, pull the needle straight out (see Figure H).
- Do not recap the needle at any time to avoid injury and infection.

Step 12. Apply pressure to 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.
- Do not re-use the prefilled syringe.

Step 13. Dispose of your prefilled syringe right away.
- Put your used prefilled syringes, needles, and sharps in a FDA-cleared sharps disposal container right away after use.
- Do not throw away (dispose of) loose needles, syringes, or prefilled syringes in your household trash. Do not recycle your used sharps disposal container.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and
  - properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

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