PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Aimovig® 70 mg
Aimovig® 140 mg

Solution for Subcutaneous Injection in Pre-filled Pen

Active ingredient:
Erenumab 70 mg/ml
Erenumab 140 mg/ml

Inactive and allergenic ingredients in the preparation: see section 2 'Before using the medicine' and section 6 'Further information'.

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1. WHAT IS THE MEDICINE INTENDED FOR?

Aimovig is intended for the prevention of migraine in adults who experience at least 4 migraine days per month when starting treatment with Aimovig.

Therapeutic group: Analgesics, antimigraine preparations.

Aimovig belongs to a group of medicines called monoclonal antibodies and works by blocking the receptor of the CGRP (calcitonin gene-related peptide) molecule and thus reduces the activity of the molecule which has been linked to migraine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient erenumab, or to any of the additional ingredients contained in the medicine (see section 6 'Further information').

Special warnings regarding use of the medicine

Before treatment with Aimovig, tell the doctor if:

- You have had an allergic reaction in the past to rubber latex. The container of this medicine contains latex rubber within the cap.
- You suffer from cardiovascular disease. Aimovig has not been studied in patients with certain cardiovascular diseases.

Refer to your doctor or get emergency medical help immediately:

- If you get any symptoms of a serious allergic reaction, such as rash or swelling, usually of the face, mouth, tongue, or throat; or difficulty breathing. Serious allergic reactions can happen within minutes, but some may happen more than one week after using Aimovig.
- Contact a doctor if you get constipation and seek medical help immediately if you develop constipation with severe or constant belly (abdominal) pain accompanied by vomiting, swelling of abdomen or bloating. Constipation can occur when treated with Aimovig. It is usually mild or moderate in intensity. Yet, some patients using Aimovig have had constipation with serious complications and have been hospitalised. Some cases have required surgery.

Children and adolescents:
There is no information regarding the safety and efficacy of use of this preparation in children and adolescents.

Drug interactions:
If you are taking, or have recently taken, or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or planning a pregnancy, consult with your doctor before using the medicine.
Pregnancy
Your doctor will decide whether you should stop using Aimovig during pregnancy.
Breastfeeding
Monoclonal antibodies like Aimovig are known to pass into breast milk during the first few days after birth, but after this initial period, Aimovig can be used. Talk to your doctor about using Aimovig while breastfeeding in order to help you decide whether you should stop breastfeeding or stop using Aimovig.

Driving and operating machinery:
Aimovig is expected to have no or negligible influence on your ability to drive and operate machinery.

Important information about some of the ingredients of the medicine:
Aimovig contains sodium.
Aimovig contains less than 1 mmol sodium (23 mg) per dose - i.e., it is essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.

The usual dose is generally:
If your doctor prescribed a 70 mg dose, you should receive one injection of Aimovig 70 mg every 4 weeks.
If your doctor prescribed a 140 mg dose, you should receive one injection of Aimovig 140 mg or two injections of Aimovig 70 mg every 4 weeks.
If you are to receive two injections of Aimovig 70 mg, the second injection must be given immediately after the first one and in a different injection area. Make sure that you inject the entire contents of both pre-filled pens.

Do not exceed the recommended dose.

How to use
Aimovig is given as an injection under your skin (subcutaneous injection). You or your caregiver can give the injection into your abdomen or your thigh. The outer area of your upper arm can also be used as an injection area, but only if someone else is giving you the injection. If you need 2 injections, they should be given in two different injection sites to avoid hardening of the skin, and should not be injected into areas where the skin is tender, bruised, red or hard.
Your doctor or nurse will instruct you or your caregiver regarding the correct way to prepare and inject Aimovig. Do not try to inject Aimovig before this training has been given.
Aimovig pre-filled pens are intended for single use of each individual pen.
For detailed instructions on how to inject, see 'Instructions for use of Aimovig pre-filled pens' at the end of this leaflet.

Duration of treatment
If you have not noticed any treatment effect after 3 months, tell your doctor, who will decide whether you should continue treatment.

If you accidentally took too high a dose
Tell your doctor if you have received more Aimovig than you should have received, or if the dose has been given earlier than required.
If you took an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine

- If you forget an Aimovig dose, take it as soon as possible after you realize it.
- Then contact your doctor, who will tell you when you should take your next dose. Follow the new schedule exactly as your doctor has instructed you.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Your symptoms may return if you stop the treatment.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Aimovig may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them. Possible side effects are listed below. Most of these side effects are mild to moderate.

Common side effects (that occur in up to 1 user in 10):

- Allergic reactions such as rash, swelling, hives (urticaria) or difficulty breathing (see 'Special warnings regarding use of the medicine' section)
- Constipation
- Itching
- Muscle cramps
- Injection site reactions, such as pain, redness and swelling in the area where the injection is given

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- mouth and lip sores
- hair loss
- rash

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking the link 'Report Side Effects of Drug Treatment' found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage Conditions:

- Keep refrigerated (2°C – 8°C). Do not freeze.
- Keep the pre-filled pen in the outer carton in order to protect from light.
- After taking the medicine out of the refrigerator, it can be stored at a temperature up to 30°C in the outer carton and should be used within 7 days. Do not return it to the refrigerator.
- Do not use the medicine if you notice that the solution contains particles, is cloudy or is distinctly yellow.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
sucrose, glacial acetic acid, polysorbate 80, sodium hydroxide, water for injection

What the medicine looks like and the contents of the package:
Clear to slightly opalescent solution, colorless to light yellow and practically free from particles.
The pack contains one single-use pre-filled pen (1 ml).

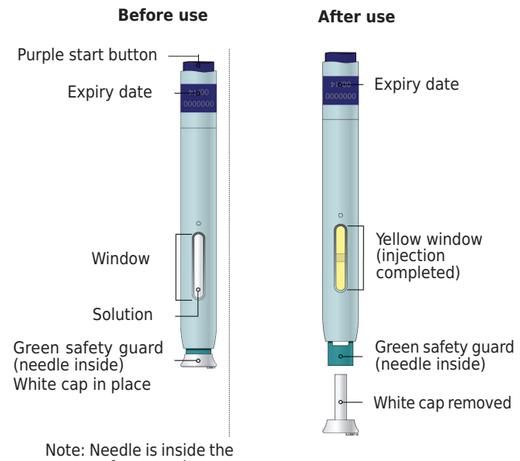
Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in June 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Aimovig 70 mg 162 89 35707
Aimovig 140 mg 164 09 36005

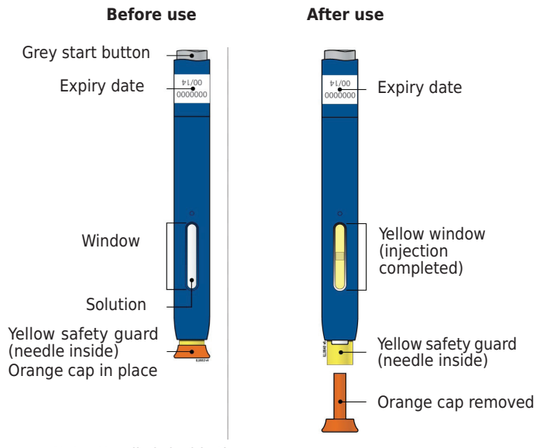
INSTRUCTIONS FOR USE OF AIMOVIG PRE-FILLED PENS

Illustration of the Aimovig 70 mg pre-filled pen (with a light blue body, purple start button, white cap and green safety guard)



Note: Needle is inside the green safety guard.

Illustration of the Aimovig 140 mg pre-filled pen (with a dark blue body, grey start button, orange cap and yellow safety guard)



Note: Needle is inside the yellow safety guard.

General:
Before you use the Aimovig pre-filled pen, read this important information:

Step 1: Prepare
Note: The prescribed dose of Aimovig is either 70 mg or 140 mg. This means that for the 70 mg dose, you must inject the contents of one 70 mg single-use pen. For the 140 mg dose you must inject the contents of either one 140 mg single-use pen or two 70 mg single-use pens, one after the other and at different injection sites.

(A)
Carefully remove Aimovig pre-filled pen(s) from the outer carton. You will have to use either one or two pens, based on the dose that was prescribed for you. Do not shake.
To avoid discomfort at the site of injection, leave the pen(s) at room temperature for at least 30 minutes before injecting.
Note: Do not try to warm the pen(s) by using a heat source such as hot water or a microwave.

(B)
Inspect the pen(s). Make sure the solution you see in the window is clear to slightly opalescent, and colorless to light yellow.
Note:

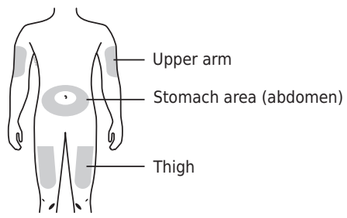
- Do not use the pen(s) if any part appears cracked or broken.
- Do not use any pen that has been dropped.
- Do not use the pen if the cap is missing or is not securely attached.

In all the cases described above, use a new pen, and if you are unsure contact your doctor or pharmacist.

(C)
Gather all the materials needed for the injection(s).
Wash your hands thoroughly with soap and water.
Place the following items on a clean and well-lit surface:

- New pen(s)
- Alcohol wipes
- Cotton balls or gauze pads
- Adhesive bandages (plasters)
- Sharps disposal container

(D)
Prepare and clean the injection site(s).



Only use one of the following injection areas:

- Thigh
- Stomach area (abdomen) (except for a 5 cm area around the navel)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection area with an alcohol wipe and let the skin dry.

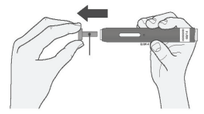
Choose a different injection area each time you give yourself an injection. If you need to use the same injection area, make sure it is not the same spot in the area that you used last time.

Note:

- After you have cleaned the area, do not touch it again before injecting.
- Do not choose an area where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

Step 2: Get ready

(E)
Pull the cap straight off, only when you are ready to inject. The injection must be administered **within 5 minutes**. It is normal to see a drop of liquid at the end of the needle or safety guard.

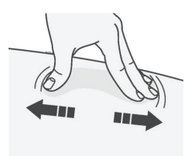


Note:

- Do not leave the cap off for more than 5 minutes. This can dry out the medicine.
- Do not twist or bend the cap.
- Do not put the cap back onto the pen once it has been removed.
- Do not put your fingers into the safety guard.

(F)
Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **one of the 2 methods**, the Stretch method **or** the Pinch method.

Stretch method
Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area of about **five** cm wide.



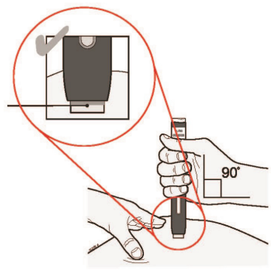
or

Pinch method
Pinch skin firmly between your thumb and fingers, creating an area of about **five** cm wide.

Note: It is important to keep skin stretched or pinched while injecting.

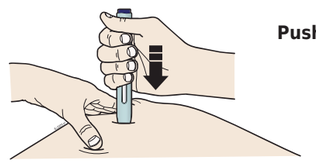
Step 3: Inject

(G)
Keep holding the stretched/pinched skin. With the cap off, put the safety guard of the pen on the skin at an angle of 90 degrees. The needle is inside the safety guard.



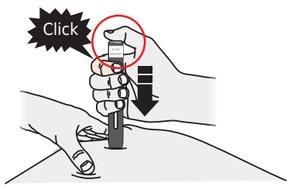
Note: Do not touch the start button yet.

(H)
Firmly push the pen down onto the skin until it stops moving.

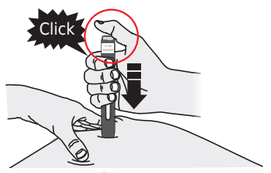


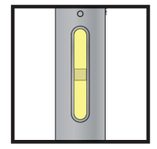
Note: You must push all the way down, but do not touch the start button until you are ready to inject.

(I)
Press the start button. You will hear a click.



(J)
Remove your thumb from the button, but keep pushing down on the skin. The injection could take about 15 seconds.





Note: When the injection is completed, the window will turn from clear to yellow and you may hear a second click.

Note:

- After you remove the pen from the skin, the needle will automatically be covered by the safety guard.
- When you remove the pen, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Contact your doctor immediately.

Step 4: Finish

(K)
Discard the used pen and the cap.
Put the used pen in a sharps disposal container immediately after use. Talk to your doctor or pharmacist about proper waste disposal.
Note:

- Do not reuse the used pen.
- Do not recycle the pen or the sharps disposal container.
- Always keep the sharps disposal container out of the reach of children.

(L)
Examine the injection area.
If there is blood on the skin, press a cotton ball or gauze pad onto the injection area. Do not rub the injection area. Apply an adhesive plaster if needed.

If your dose is 140 mg and you are using two 70 mg pens, repeat steps 1(D) to 4 with the second pen, and in a different area, to inject the full dose.