Package leaflet: Information for the user

Aimovig 70 mg solution for injection in pre-filled pen
Aimovig 140 mg solution for injection in pre-filled pen
erenumab

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 Aimovig is and what it is used for

Aimovig contains the active substance erenumab. It belongs to a group of medicines called monoclonal antibodies.

Aimovig works by blocking the activity of the CGRP molecule, which has been linked to migraine (CGRP stands for calcitonin gene-related peptide).

Aimovig is used to prevent migraine in adults who have at least 4 migraine days per month when starting treatment with Aimovig.

2. What you need to know before you use Aimovig

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

Warnings and precautions
Talk to your doctor before using Aimovig:
- if you have ever had an allergic reaction to rubber latex. The container of this medicinal product contains latex rubber within the cap.
- if you suffer from a cardiovascular disease. Aimovig has not been studied in patients with certain cardiovascular diseases.

Talk 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 and vomiting, swelling of abdomen or bloating. Constipation can occur when treated with Aimovig. It is usually mild or moderate in intensity. However, some patients using Aimovig have had constipation with serious complications and have been hospitalised. Some cases have required surgery.

Children and adolescents
Do not give this medicine to children or adolescents (under 18 years old) because the use of Aimovig has not been studied in this age group.

Other medicines and Aimovig
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 or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Pregnancy
Your doctor will decide whether you should stop using Aimovig during pregnancy.

Breast-feeding
Monoclonal antibodies like Aimovig are known to pass into breast milk during the first few days after birth, but after this first period Aimovig can be used. Talk to your doctor about using Aimovig while breast-feeding in order to help you decide whether you should stop breast-feeding or stop using Aimovig.

Driving and using machines
Aimovig is unlikely to affect your ability to drive and use machines.

Aimovig contains sodium
Aimovig contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Aimovig

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

If your doctor prescribes the 70 mg dose you should have one injection once every 4 weeks. If your doctor prescribes the 140 mg dose you should have either one injection of Aimovig 140 mg or two injections of Aimovig 70 mg once every 4 weeks. If you are having two injections of Aimovig 70 mg, the second injection must be given immediately after the first one at a different injection site. Make sure that you inject the entire contents of both pens.

Aimovig is given as an injection under your skin (known as a 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 site, but only if someone else is giving you the injection. If you need 2 injections, they should be given in different sites to avoid hardening of the skin and should not be given into areas where the skin is tender, bruised, red or hard.

Your doctor or nurse will give you or your caregiver training in the right way to prepare and inject Aimovig. Do not try to inject Aimovig until this training has been given.

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

Aimovig pens are for single use only.

For detailed instructions on how to inject Aimovig, see "Instructions for use of Aimovig pre-filled pen" at the end of this leaflet.

If you use more Aimovig than you should
If you have received more Aimovig than you should or if the dose has been given earlier than it should have been, tell your doctor.

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

If you stop using Aimovig
Do not stop using Aimovig without talking to your doctor first. Your symptoms may return if you stop the treatment.

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.

Possible side effects are listed below. Most of these side effects are mild to moderate.

Common: may affect up to 1 in 10 people
- allergic reactions such as rash, swelling, hives or difficulty breathing (see section 2)
- constipation
- itching
- muscle spasms
- injection site reactions, such as pain, redness and swelling where the injection is given.

Not known (frequency cannot be estimated from the available data)
- skin reactions such as rash, itching, hair loss or mouth/lip sores.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aimovig

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

Keep the pen(s) in the outer carton in order to protect from light. Store in a refrigerator (2°C – 8°C). Do not freeze.

After Aimovig has been taken out of the refrigerator, it must be kept at room temperature (up to 25°C) in the outer carton and must be used within 7 days, or else discarded. Do not put Aimovig back in the refrigerator once it has been removed.

Do not use this medicine if you notice that the solution contains particles, is cloudy or is distinctly yellow.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. There may be local regulations for disposal. These measures will help protect the environment.

6. Contents of the pack and other information

What Aimovig contains
- The active substance is erenumab.
- Aimovig 70 mg solution for injection in pre-filled pen contains 70 mg erenumab.
- Aimovig 140 mg solution for injection in pre-filled pen contains 140 mg erenumab.
- The other ingredients are sucrose, polysorbate 80, sodium hydroxide, glacial acetic acid, water for injections.

What Aimovig looks like and contents of the pack
Aimovig solution for injection is clear to opalescent, colourless to light yellow, and practically free from particles.

Aimovig is available in packs containing one single-use pre-filled pen and in multipacks containing 3 (3x1) pre-filled pens.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu