

PONTEVIA 120MG SOLUTION FOR INJECTION IN PRE-FILLED PEN

PONTEVIA 120MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

Galcanezumab 120 mg

What is in this leaflet

1. What Pontevia is used for
2. How Pontevia works
3. Before you use Pontevia
4. How to use Pontevia
5. While you are using it
6. Side effects
7. Storage and Disposal of Pontevia
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What Pontevia is used for

Pontevia is a prescription medicine used to prevent migraine in adult patients who have at least 4 migraine days per month.

How Pontevia works

Pontevia contains galcanezumab, a medicine that stops the activity of a naturally occurring substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP.

Pontevia can reduce the frequency of migraine headache and improve your quality of life. It starts working in about a week.

Before you use Pontevia

- When you must not use it

If you are allergic to galcanezumab or any of the other ingredients of this medicine (see **Product Description** section).

- Before you start to use it

Talk to your doctor, nurse or pharmacist before using Pontevia.

Pontevia can potentially cause serious allergic reactions. You must look out for signs of these reactions while you are using Pontevia (see **Side Effects**).

Tell your doctor, nurse or pharmacist if you have high blood pressure.

Tell your doctor, nurse or pharmacist if you have circulation problems in your fingers and toes.

Children and adolescents: Pontevia should not be given to children and adolescents under 18 years of age because it has not been studied in this age group.

Pregnancy and lactation: If you are a woman able to have children, you are advised to avoid becoming pregnant while using Pontevia.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is preferable to avoid the use of Pontevia in 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 before using this medicine. You and your doctor should decide if you should breast-feed and use Pontevia.

Driving and using machines: Galcanezumab could have a minor effect on your ability to drive and use machines. Some patients have had vertigo whilst using Pontevia.

- Taking other medicines

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

How to use Pontevia

- How much to use

The first time you receive Pontevia your doctor or nurse will inject two pens or syringes (total 240 mg). After

the first dose, you will use one pen or syringe (120 mg) every month.

- When to use it

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

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your Pontevia injection after proper training.

Pontevia pre-filled pen or pre-filled syringe is for single use only and contains one dose of Pontevia (120 mg). The pre-filled pen or pre-filled syringe must not be shaken.

Read the "Instructions for Use" for the pen or syringe carefully before using Pontevia.

- How long to use it

Pontevia is for long-term treatment. Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

- If you forget to use it

Do not take a double dose to make up for forgotten injection.

If you have forgotten to inject a dose of Pontevia, inject the missed dose as soon as possible and then inject the next dose after a month from that date.

- If you use too much (overdose)

If you have injected more Pontevia than you should, e.g. if after the first dose of 240 mg, you have injected it twice in a single month, or if anyone else has accidentally used Pontevia, contact your doctor immediately.

While you are using it**- Things you must do**

Take your medicine exactly as your doctor, pharmacist or nurse has told you.

- Things you must not do

You should not stop using Pontevia without speaking to your doctor first. If you have any further questions on the use of this medicine, 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.

- Things to be careful of**Look out for side effects**

Tell your doctor or get emergency medical help straight away if you notice any symptoms of side effects (see **Side Effects** section).

Side effects

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

Serious side effects

Pontevia may cause serious side effects such as allergic reactions as follows:

- itching/hives
- rash
- trouble breathing

Inform your doctor, nurse or pharmacist if you have any of the following symptoms, which may be part of an allergic reaction:

- swelling of the face, mouth, tongue or throat
- trouble breathing

High blood pressure: High blood pressure or worsening of high blood pressure can happen after receiving Pontevia. Contact your doctor, nurse or pharmacist if you have an increase in blood pressure.

Raynaud's phenomenon: A type of circulation problem can worsen or happen after receiving Pontevia. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale, to blue, to red. Contact your doctor, nurse or pharmacist if these symptoms occur.

The most common side effect of Pontevia is the injection site reactions.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Pontevia**- Storage**

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the pen or 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.

Store in the original package in order to protect from light.

Pontevia may be stored unrefrigerated for single period up to 7 days when stored at temperatures up to 30°C. If the pen or syringe is stored at a higher temperature or for a longer period it must be discarded.

Do not use this medicine if you notice that the pen or syringe is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.

- Disposal

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

Product Description**- What it looks like**

Pontevia is a solution for injection in a clear glass syringe. Its colour may vary from colourless to slightly yellow to slightly brown.

The syringe is encased in a disposable, single-dose pen for pre-filled pen.

Pack sizes of 1 pre-filled pen or pre-filled syringe.

- Ingredients**- Active ingredient**

- Galcanezumab

- Inactive ingredients

- L-histidine
- L-histidine hydrochloride monohydrate
- Polysorbate 80
- Sodium chloride
- Water for injections

- MAL number(s):

Pontevia 120mg Solution for Injection in Pre-Filled Pen – MAL21016002AZ
Pontevia 120mg Solution for Injection in Pre-Filled Syringe – MAL21016001AZ

Manufacturer

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana (IN)
46285, United States (USA)

Product Registration Holder

Zuellig Pharma Sdn Bhd
No. 15, Persiaran Pasak Bumi,
Seksyen U8, Perindustrian Bukit
Jelutong, 40150 Shah Alam, Selangor
Darul Ehsan, Malaysia

Date of Revision

03/11/2025

Serial Number

NPRA(R3)20/011