

PASURTA[®] INJECTION

Erenumab (70 mg/ml & 140 mg/ml)

What is in this leaflet

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

What Pasurta is used for

Pasurta is a medicine used to prevent migraine in adults who have at least 4 migraine days per month. It contains the active substance erenumab, which belongs to a group of medicines called anti-Calcitonin Gene-Related Peptide (CGRP) receptor antibody.

How Pasurta works

Pasurta works by blocking the activity of CGRP molecule, which has been linked to migraine.

Before you use Pasurta

- When you must not use it

If you have had an allergic reaction to Pasurta or to any of its ingredients. See “**Product Description**” section below for all ingredients. Ask your doctor if you are not sure.

Tell your healthcare provider 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 Pasurta.

If you have severe constipation or constipation associated with symptoms such as severe or constant belly pain, vomiting, swelling of belly or bloating. Severe constipation can happen after receiving Pasurta. In some cases, patients have been hospitalized or needed surgery.

- Before you start to use it

Children and adolescents (below 18 years)

The use of Pasurta has not been studied in children under 18 years of age.

Older people (65 years or above)

You can use Pasurta if you are aged 65 years or over at the same dose as for other adults.

Pregnancy and lactation

Pasurta has not been studied in pregnant women. It is not known if Pasurta will harm your unborn baby. Talk to your doctor if you are trying to get pregnant or think you may be pregnant before taking Pasurta. Your doctor will discuss with you the potential risks of taking Pasurta during pregnancy.

It is not known if Pasurta passes through breast milk. It is important to tell your doctor if you are breastfeeding or plan to breastfeed. Your doctor will then help you decide if you should stop breastfeeding, or stop taking Pasurta.

- Taking other medicines

Before you take Pasurta, tell your doctor or pharmacist if you are taking any other medicines, including medicines obtained without a prescription, because these might interact with Pasurta.

How to use Pasurta

See the detailed “Instructions for Use” with this leaflet for instructions about the right way to store, prepare, and give your Pasurta injections at home.

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

Do not exceed the recommended dose prescribed by your doctor.

- How much to use

The usual dose of Pasurta is 70 mg once monthly. Your doctor might also decide you need 140 mg once a month. Take Pasurta exactly as instructed by your doctor.

- When to use it

Once a month.

- How long to use it

Continue taking Pasurta once a month for as long as your doctor tells you. If you have questions about how long to take Pasurta, talk to your doctor or pharmacist.

- If you forget to use it

If you forget to take Pasurta dose, take it as soon as you can after the missed dose. Then, contact your doctor who will tell you when you should schedule your next doses, and follow that schedule exactly as your doctor has told you.

- If you use too much (overdose)

If you take more Pasurta than you should, contact your doctor or pharmacist.

While you are using it

- Things you must do

Pasurta comes in a prefilled syringe. Each prefilled syringe is for a single injection.

Your doctor or nurse will give you or your caregiver training in the right way to prepare and inject. Do not try to inject Pasurta until you or your caregiver have been shown the right way by your doctor or nurse.

Before injection, let Pasurta sit at room temperature (up to 30°C) for at least 30 minutes. This will make the injection more comfortable.

Pasurta is given as an injection under the skin (subcutaneous or SC). You or your caregiver can administer the injection into your abdomen, thigh or (only if someone else is giving you the injection) into the outer area of the upper arm.

Each syringe contains 70 mg or 140 mg Pasurta. If you need 2 injections, the second injection must be given immediately after the first. Make sure that you inject the entire contents of syringe.

- Things you must not do

Do not give an injection in an area of the skin that is tender, bruised, red or hard. Also do not use the same spot as used for a previous injection.

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

Do not use this medicine if the liquid contains easily visible particles, is cloudy or distinctly yellow.

- Things to be careful of

Pasurta contains natural rubber latex within the cap of the prefilled syringe. It may cause allergic responses in individuals who are sensitized to latex. Tell your healthcare provider if you are allergic to latex.

Pasurta is unlikely to affect your ability to drive and use machines.

Side effects

As with all medicines, patients treated with Pasurta may experience side effects, although not everybody gets them.

Possible side effects include the following listed below. Most of these side effects are mild to moderate. If these side effects become severe, please tell your doctor or pharmacist.

Common: *may affect up to 1 in every 10 people*

- Signs and symptoms of pain, redness, swelling at the injection site (injection site reactions)
- Constipation
- Muscle spasm
- Itching

Not known: *frequency cannot be estimated from the available data*

- Allergic reactions such as rash or swelling or sometimes difficulty breathing
- Hair loss
- Mouth/lip sores

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist or healthcare provider.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Pasurta

- Storage

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 carton.

- Store in a refrigerator at 2°C to 8°C, in the original carton.
- After Pasurta is removed from the refrigerator, it should be kept at controlled room temperature (up to 30°C) in the original carton and must be used within 7 days. Do not put Pasurta back in the refrigerator once they have reached room temperature.
- Protect Pasurta from direct light and do not expose to temperatures above 30°C.
- Do not freeze.
- Do not shake
- Keep Pasurta and all medicines out of reach of children.

- Disposal

Do not throw away any medicines in wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use.

Product Description

- What it looks like

Pasurta is a solution that is clear, colorless to yellowish, and practically free from particles.

Each pack contains one single-use prefilled syringe.

- Ingredients

- Active ingredient

The active substance of Pasurta is crenumab.

- Inactive ingredients

The other ingredients of Pasurta are:

- sucrose,
- glacial acetic acid
- polysorbate 80
- water for injection
- sodium hydroxide.

- MAL number:

70 mg/ml: MAL19056108ARZ

140 mg/ml: MAL20096004ACRZ

Manufacturer

Amgen Manufacturing Limited
State Road 31, Km 24.6 Juncos,
Puerto Rico 00777-4060,
United States (USA)

Releaser

Alcon-Couvreur NV,
Rijksweg 14,
Puurs 2870,
Belgium

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Version

Pasurta 70&140 23Mar2022

Date of revision

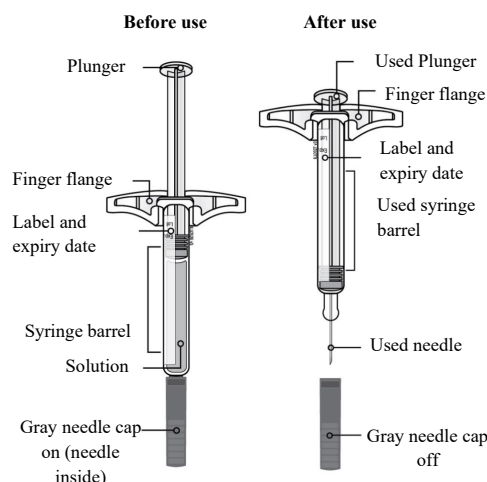
3 June 2022

Serial Number

NPRA(R3/01)22072022/0210

INSTRUCTION FOR USE OF THE 70 MG/ML AND 140 MG/ML SOLUTION FOR INJECTION IN A SINGLE-USE PREFILLED SYRINGE

Single-Use Prefilled Syringe



Important: Needle is inside the grey needle cap.

Before you use a Pasurta prefilled syringe, read this important information:

Storing your Pasurta prefilled syringe.

- Keep the syringe out of the sight and reach of children.
- Keep the syringe in the original carton to protect from light or physical damage.
- The syringe should be kept in the refrigerator at 2°C to 8°C.
- Throw away Pasurta that has been left at room temperature (up to 30°C) for more than 7 days.
- Do not store the syringe in extreme heat or cold. For example, avoid storing in your car.
- Do not freeze.

Using your Pasurta prefilled syringe

- Do not try to inject Pasurta before receiving training from the doctor or nurse.
- Do not use a syringe after the expiry date stated on the label.
- Do not shake the syringe.
- Do not remove the gray needle cap from the syringe until you are ready to inject.
- Do not freeze or use the syringe if it has been frozen.

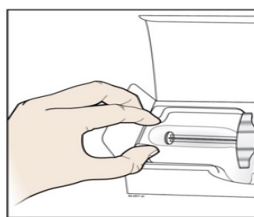
- Do not use a syringe if it has been dropped on a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new syringe, and contact your healthcare provider (doctor, nurse or pharmacist).
- This product contains natural rubber latex within the gray needle cap. The product may cause allergic responses in individuals who are sensitized to latex. Tell your healthcare provider if you are allergic to latex.
- For more information or help contact your healthcare provider.

Step 1: Prepare

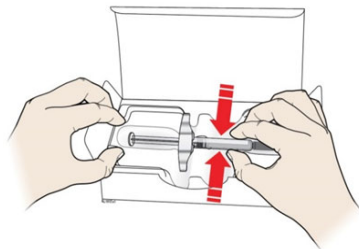
Read this before you inject.

- Check your prescription.
- Your healthcare provider has prescribed a 70 mg or a 140 mg dose.
- For a 70 mg dose, inject one syringe of 70 mg/mL.
- For a 140 mg dose, inject either two syringes of 70mg/mL one after the other, or one syringe of 140 mg/mL if you were prescribed the 140mg/mL formulation.
- To avoid discomfort at the site of injection, leave the syringes at room temperature for at least 30 minutes before injecting.

A) Remove the Pasurta prefilled syringe(s) from the carton. Grab the syringe barrel to remove the syringe(s) from the tray.

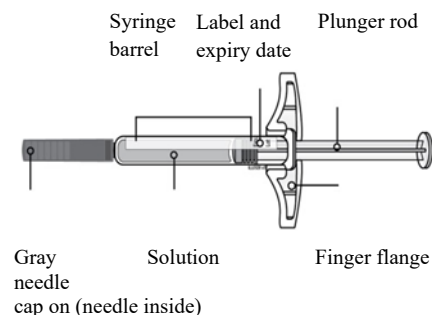


Place your finger and thumb on the edge of tray to secure it while you remove the syringe(s).



Hold the syringe(s) at the barrel (see arrows).

B) Inspect the Pasurta prefilled syringe(s). Always hold the syringe(s) by the syringe barrel. Make sure the medicine in the syringe(s) is clear and colorless to slight yellow. Leave the syringe(s) at room temperature for at least 30 minutes before injecting. Do not use the syringe(s) if the medicine is cloudy or discolored or contains flakes or particles. Do not use the syringe(s) if any part appears cracked or broken. Do not use the syringe(s) if the syringe has been dropped. Do not use the syringe(s) if the gray needle cap is missing or not securely attached. Do not use the syringe(s) if the expiry date printed on the label has passed. In all cases, use a new syringe(s), and in case of doubts contact your healthcare provider.



C) Gather all materials needed for the injections.

Wash your hand thoroughly with soap and water.

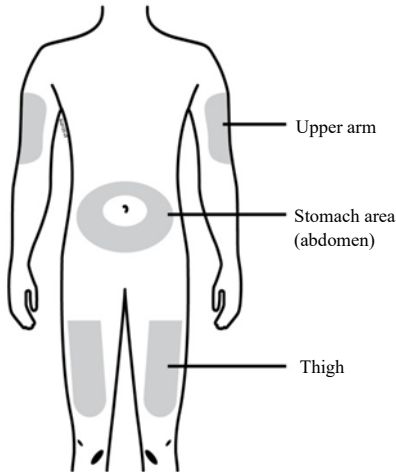
On a clean, well-lit work surface, place the:

- One or two new syringes (dependent on your prescribed dose)
- Alcohol wipe(s)
- Cotton ball(s) or gauze pad(s)
- Adhesive bandage(s)
- Sharps disposal container



D) Prepare and clean the injection site(s). Only use these injection sites:

- The thigh
- Stomach area (abdomen), except for a five cm area right around the navel
- Outer area of upper arm (only if someone else is giving you the injection)



Clean your injection site with an alcohol wipe. Let your skin dry.

Do not touch this area again before injecting.

Choose a different site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the injection site you used for a previous injection.

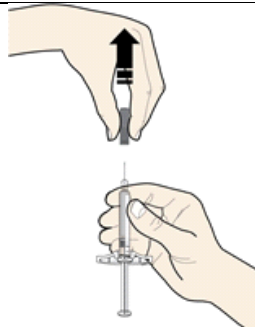
Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting directly into a raised, thick, red or scaly skin patch or lesion, or areas with scars or stretch marks.

Step 2: Get ready

E) Pull the gray needle cap straight out and away from your body, only when you are ready to inject. Do not leave the gray needle cap off for more than five minutes. This can dry out the medicine. It is normal to see a drop of liquid at the end of the needle.

Do not twist or bend the gray needle cap. Do not put the gray needle cap back onto the syringe(s).

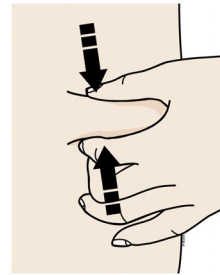
Do not remove the gray needle cap from the syringe(s) until you are ready to inject.



F) Pinch the injection site to create a firm surface.

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

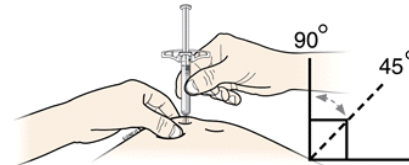
Important: Keep skin pinched while injecting.



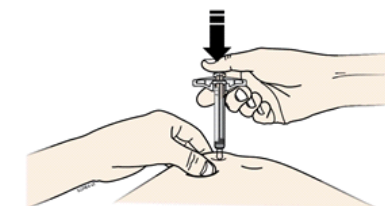
Step 3: Inject

G) While pinching, with the gray needle cap off, insert the syringe(s) into the skin at an angle of 45 to 90 degrees.

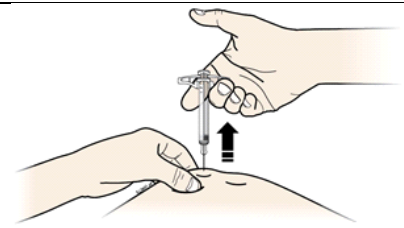
Do not place your finger on the plunger rod while inserting the needle.



H) Using slow and constant pressure, push the plunger rod all the way down until it stops moving.



I) When done, release your thumb, and gently lift the syringe(s) off of the skin.



Important: When you remove the syringe(s), if it looks like the solution is still in the syringe(s) barrel, this means you have not received a full dose. Call your healthcare provider immediately.

Step 4: Finish

J) Discard the used syringe(s) and the gray needle cap.

Put the used Pasurta syringe(s) in a sharps disposal container right away after use. Do not throw away (dispose of) the syringe(s) in your household trash.

Talk with your healthcare provider about proper disposal. There may be local regulations for disposal.

Do not reuse the syringe(s).

Do not recycle the syringe(s) or sharps disposal container or throw them into household trash.

Important: Always keep the sharps disposal container out of the sight and reach of children.



K) Examine the injection site

If there is blood, press the cotton ball or gauze pad on your injection site. Do not rub the injection site. Apply an adhesive bandage if needed.

If you were prescribed the 140 mg dose using two 70 mg/ml syringes repeat steps 1D to 3 with the second syringe to inject your full dose.