NOVARTIS

PASURTA®

70 mg/mL solution for injection in pre-filled syringe

140 mg/mL solution for injection in pre-filled syringe

Patient Information Leaflet

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SCHEDULING STATUS: S4

Pasurta® 70 mg/mL solution for injection in pre-filled syringe

Pasurta® 140 mg/mL solution for injection in pre-filled syringe

Erenumab

Contains sugar (sucrose)

Read all of this leaflet carefully before you start using Pasurta

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other healthcare provider.
- Pasurta has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Pasurta is and what it is used for
2. What you need to know before you use Pasurta
3. How to use Pasurta
4. Possible side effects
5. How to store Pasurta
6. Contents of the pack and other information

1. What Pasurta is and what it is used for

What Pasurta is

Pasurta 70 mg/mL solution for injection in a pre-filled syringe.

Pasurta 140 mg/mL solution for injection in a pre-filled syringe.

Pasurta contains the active substance erenumab, which belongs to a group of medicines called anti-Calcitonin Gene-Related Peptide (CGRP) receptor antibody.

What Pasurta is used for

Pasurta is a medicine used to prevent migraine.

The use of Pasurta has not been studied in children under 18 years of age. It is not known whether Pasurta is safe and effective in children.

How Pasurta works

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

If you have any questions about how Pasurta works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

2. What you need to know before and while you use Pasurta

Pasurta should not be administered to you:

- if you are hypersensitive (allergic) to erenumab or any of the other ingredients of Pasurta (listed in section 6).

Warnings and precautions

If this applies to you, tell your doctor or pharmacist or healthcare provider before using or receiving Pasurta:

- If you have had an allergic reaction to Pasurta or to any of its ingredients. See “What Pasurta contains” section below for all ingredients. Ask your doctor if you are not sure.
- The removable cap of Pasurta pre-filled syringe contains dry natural rubber latex. It may cause allergic responses in individuals who are sensitized to latex.

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 stomach pain, vomiting, swelling of your stomach or bloating. Severe constipation can happen after receiving Pasurta. In some cases, people have been hospitalized or needed surgery.

Children and adolescents

The use of Pasurta has not been studied in children under 18 years of age and therefore Pasurta is not recommended for use in paediatric patients.

Older people (65 years or above)

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

Other medicines and Pasurta (interactions with other medicines including vaccines or biologics)

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional 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.

Pregnancy and breastfeeding and fertility

Safe use during pregnancy has not been established, therefore, Pasurta is not recommended for use during pregnancy.

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

It is expected that Pasurta is excreted in breast milk. Mothers who are breastfeeding their babies should not take Pasurta.

It is important to tell your doctor if you are breastfeeding or plan to breastfeed.

Driving and using machines

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

3. How to use Pasurta

Do not share medicines prescribed for you with any other person.

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 (see also website address "www.Pasurtatraining.eu" with a link to a video showing how Pasurta should be administered).
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 Pasurta to take

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

70 mg/mL solution for injection

If your doctor prescribed the 70 mg dose, you must get one injection (subcutaneous) in your abdomen, thigh, or upper arm.

If your doctor prescribed the 140 mg dose, you must get two 70 mg injections (subcutaneous) in your abdomen, thigh, or upper arm, one right after the other for each dose. If you use the same injection area, each injection should be given at a different spot.

140 mg/mL solution for injection

You must get one injection (subcutaneous) in your abdomen, thigh, or upper arm.

How to use Pasurta

- Pasurta comes in a pre-filled syringe. Your doctor will prescribe the type that is best for you. Each pre-filled 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 25 °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.
- 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.
- 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 the syringe.
- Pasurta contains natural rubber latex within the cap of the pre-filled syringe. It may cause allergic responses in individuals who are sensitized to latex. Tell your healthcare provider if you are allergic to latex.

How long to take Pasurta

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 your pharmacist.

If you take more Pasurta than you should

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

If you forget to take Pasurta

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 stop using Pasurta

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

Ask your doctor if you have any further questions on how to use Pasurta.

4. Possible side effects

Pasurta can have side effects.

Not all side effects reported for Pasurta are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Pasurta, please consult your healthcare provider for advice.

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.

Frequent side effects

- 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.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Pasurta.

5. How to store Pasurta

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 25 °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 25 °C.
- Do not freeze.
- Do not shake.

- Keep Pasurta and all medicines out of the sight and reach of children.
- 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.
- Do not use this medicine if the liquid contains easily visible particles, is cloudy or distinctly yellow.

6. Contents of the pack and other information

What Pasurta contains

The **active substance** of Pasurta is erenumab.

The **other ingredients** of Pasurta are: sucrose, glacial acetic acid, polysorbate 80, water for injection, sodium hydroxide.

This information might differ in some countries.

What Pasurta looks like and contents of the pack

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

Each pack contains one or two 70 mg/mL or one 140 mg/mL single-use pre-filled syringe

This information might differ in some countries.

Holder of Certificate of Registration

Novartis SA (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg, 2090

South Africa

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Registration numbers

Pasurta 70 mg/mL solution for injection in a pre-filled syringe: 54/7.3/0587

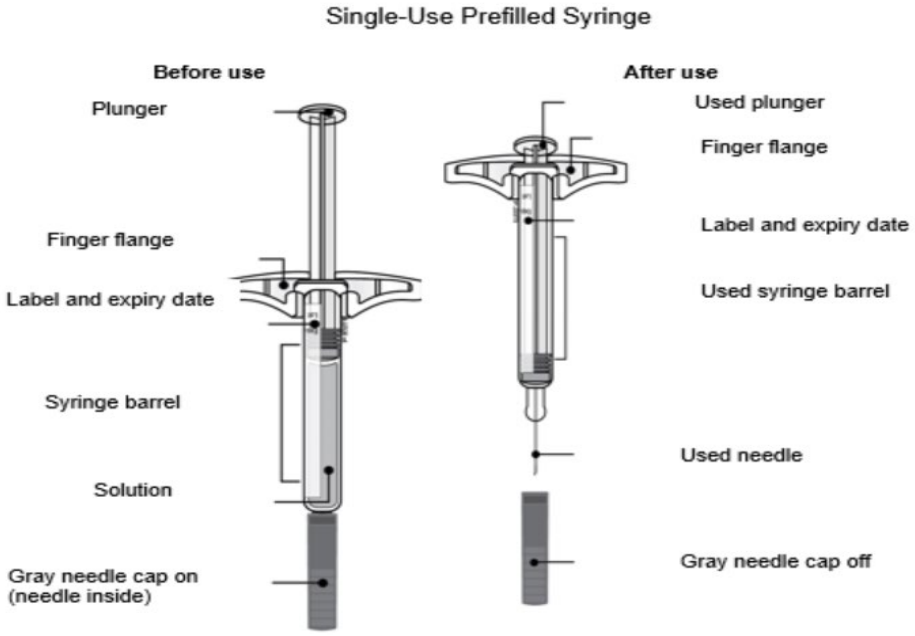
Pasurta 140 mg/mL solution for injection in a pre-filled syringe: 54/7.3/0588

Access to the corresponding Professional Information

TBA

INSTRUCTIONS FOR USE AND HANDLING

Instruction for use of the 70 mg/mL and 140 mg/mL Solution for injection in Single-Use pre-filled Syringe



Important: Needle is inside the grey needle cap.

Important

Before you use a Pasurta pre-filled syringe, read this important information:

Storing your Pasurta pre-filled 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 25 °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 pre-filled 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 grey 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 grey 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 140 mg dose.

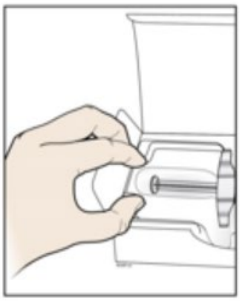
For a 70 mg dose, inject one syringe of 70 mg/mL.

For a 140 mg dose, inject either two syringes of 70 mg/mL one after the other, or one syringe of 140 mg/mL if you were prescribed the 140 mg/mL formulation.

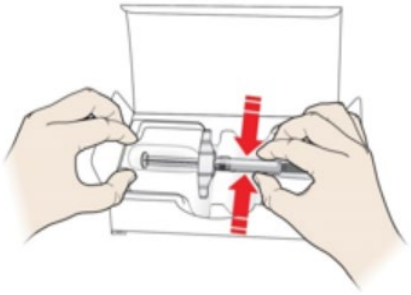
To avoid discomfort at the site of injection, leave the syringes at room temperature for at least 30 minutes before injecting.

A) Remove the Pasurta pre-filled 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 the tray to secure it while you remove the syringe(s).



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

B) Inspect the Pasurta pre-filled syringe(s).

Always hold the syringe(s) by the syringe barrel.

Make sure the medicine in the syringe(s) is clear and colourless to slightly 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 discoloured or contains flakes or particles.

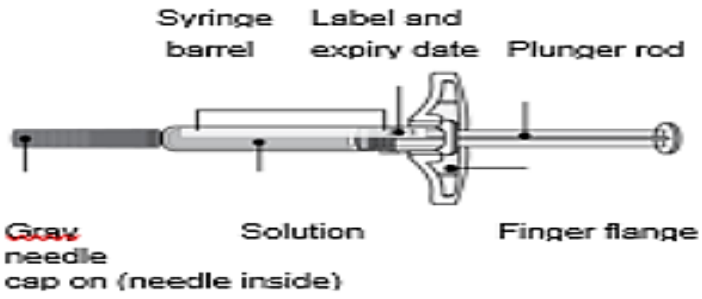
Do not use the syringe(s) if any part appears cracked or broken.

Do not use the syringe(s) if the syringe has been dropped.

Do not use the syringe(s) if the grey 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, and in case of doubts contact your healthcare provider.



C) Gather all materials needed for the injections. Wash your hands thoroughly with soap and water.

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

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

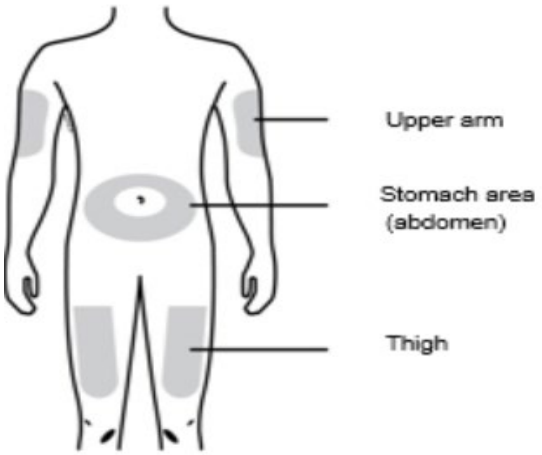




D) Prepare and clean the injection site(s).

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 grey needle cap straight out and away from your body, only when you are ready to inject.

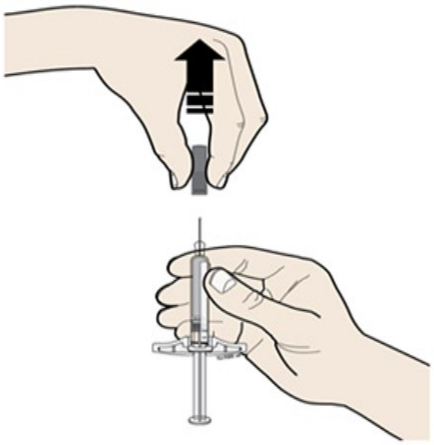
Do not leave the grey needle cap off for more than five minutes. This can dry out the medicine.

It is normal to see a drop of liquid at the end of the needle.

Do not twist or bend the grey needle cap.

Do not put the grey needle cap back onto the syringe.

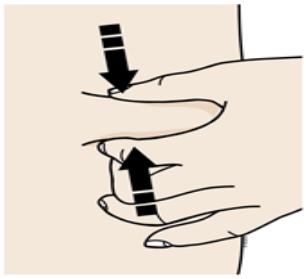
Do not remove the grey needle cap from the syringe until you are ready to inject.



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

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

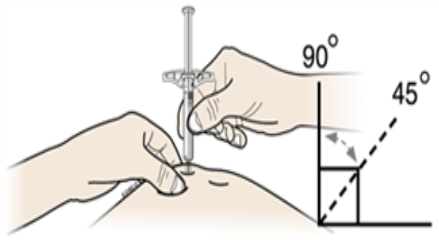
Important: Keep skin pinched while injecting.



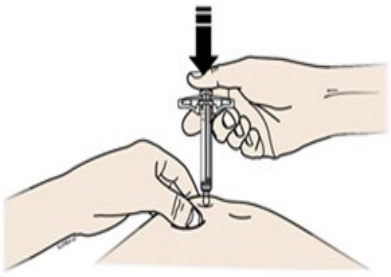
Step 3: Inject

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

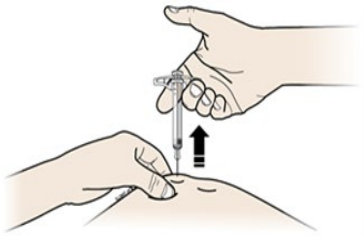
Do not place your finger on the plunger rod while inserting the needle.



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 off of the skin.



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

Step 4: Finish

J) Discard the used syringe and the grey needle cap.

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

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

Do not reuse the syringe.

Do not recycle the syringe 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 a 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 a full dose.