

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

This medicine is dispensed with a doctor's prescription only

WAINUA®

Solution for subcutaneous injection

Pre-filled pen

For subcutaneous use only

Each pre-filled pen (0.8 ml) contains:

Eplontersen (as eplontersen sodium) 45 mg

For inactive ingredients (and allergens) in the preparation - please see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any 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?

WAINUA is indicated for the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 and 2 polyneuropathy.

Therapeutic group

Other nervous system drugs.

In people with this disease, the protein transthyretin (TTR) is defective and breaks easily. This causes it to clump together and form so-called amyloid deposits, which can build up around or within the nerves, and other places in the body and stop them from working normally.

Wainua works by lowering the amount of TTR protein made by the liver. As a result, there is less TTR protein in the blood to form amyloid deposits and this can help to reduce the symptoms of the disease.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine (see section 6).

Special warnings regarding use of the medicine

You will need vitamin A supplements during treatment with Wainua. This medicine lowers the amount of vitamin A in your blood. Your doctor will check your vitamin A levels before treatment.

- Your doctor will ask **you to take an oral vitamin A supplement daily** during treatment.

Signs of low vitamin A can include poor vision especially at night, dry eyes, hazy or cloudy vision, or eye inflammation (redness, pain, excess tears or other discharge, or feeling that something is in the eye).

- **Talk to your doctor if you notice problems with vision** or any other eye problems while using Wainua. If necessary, your doctor will refer you to an eye specialist for a check-up.

You should confirm you are not pregnant before starting treatment with Wainua. Both too high and too low levels of vitamin A can harm the development of your unborn child. Women of child-bearing age **should practice effective contraception** during treatment with Wainua (see section “Pregnancy and breast-feeding” later in this leaflet).

- Vitamin A levels may remain low for more than 15 weeks after the last dose of Wainua.
- **Tell your doctor if you are planning to become pregnant.** Your doctor will tell you to stop taking Wainua and vitamin A supplementation. Your doctor

will also ensure that your vitamin A levels have returned to normal before you attempt to get pregnant.

- **Tell your doctor if you have an unplanned pregnancy during treatment.**

Your doctor will tell you to stop taking Wainua. In the first 3 months of your pregnancy, your doctor may tell you to stop taking vitamin A supplementation. During the last 6 months of your pregnancy, your doctor may tell you to resume the vitamin A supplementation if your vitamin A levels have not yet returned to normal because of the increased risk of vitamin A deficiency during the last 3 months of your pregnancy.

Children and adolescents:

No information regarding the safety and efficacy of Wainua in children and adolescents under 18 years of age. Wainua should not be used in children and adolescents under 18 years of age.

Drug interactions:

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

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Women of childbearing age

Wainua will reduce the level of vitamin A in your blood, vitamin A is important for normal development of the fetus (see section “Warnings and precautions” earlier in this leaflet).

- If you are a woman who can become pregnant, you should use **effective contraception** during treatment with Wainua.
- Talk to your doctor or nurse about suitable methods of contraception.
- You should confirm you are not pregnant before starting treatment with Wainua.

- **Tell your doctor** if you are planning to become pregnant or if you are pregnant during treatment. Your doctor will advise you to stop taking Wainua.

Pregnancy

There are no data on the use of Wainua in pregnant women. Do not use Wainua if you are pregnant or of childbearing age and not using contraception.

Breast-feeding

It is not known whether the active substance of Wainua can pass into breast milk. A risk to the breastfed child cannot be excluded. Before you start treatment, tell your doctor if you are breast-feeding or planning to breast-feed. Your doctor may tell you to stop taking Wainua.

Driving and using machines:

Wainua has no or negligible influence on your ability to drive and use machines.

Important information about some of this medicine's ingredients

Wainua contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per dose of 0.8 mL, i.e. essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined by the doctor only. The recommended dosage is usually an injection of 45 mg once every month.

Wainua comes as single use pre-filled pen. Wainua is given as an injection under the skin (subcutaneous use). The injection can be done in the belly area (abdomen) or upper thigh region. If given by a carer or health care professional, Wainua can also be given in the back of your upper arm. Do not inject the

medicine into skin that is bruised, tender, red or hard, or into scars or damaged skin. The area around the belly button (navel) should be avoided.

You and your doctor or nurse will decide if Wainua should be injected by yourself, by your carer, or by a healthcare professional. You or your carer will receive training on the right way to prepare and inject this medicine. Read the 'Instructions for Use' carefully before using the pre-filled pen (provided in a separate booklet).

Your doctor will tell you how long you need to receive Wainua. Do not stop treatment unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

Do not exceed the recommended dose.

If you use more Wainua than recommended

If you took an overdose, if you inject too much Wainua, or if a child has accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room, and bring the package of the medicine with you. Do this even if you have no symptoms.

If you forget to use Wainua

If you miss your dose of Wainua, have your next dose as soon as possible, and continue your monthly injections from then on. Do not administer a double dose.

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Wainua may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effect - effects occurring in more than 1 of 10 users:

- Low levels of vitamin A, as seen in blood tests

Common side effects – effects occurring in 1-10 of 100 users:

- vomiting
- redness (erythema), itching (pruritus) and pain where the injection was given.
- high levels of protein in the urine (Proteinuria).

Side effects of unknown incidence (effects the incidence of which has not yet been determined):

- Partial or complete atrioventricular heart block.

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

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on 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 TO STORE THE MEDICINE?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants 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.
- **Store in a refrigerator** (2°C to 8°C) in the original packaging in order to protect from light. Do not freeze.
- If necessary, Wainua may be stored outside the refrigerator at a temperature below 30°C **for up to 6 weeks** in the original carton. Dispose of unrefrigerated Wainua if it is not used within 6 weeks.

6. Additional Information

In addition to the active ingredient, the medicine also contains:

Sodium chloride; Disodium phosphate, Sodium dihydrogen phosphate dihydrate; Hydrochloric acid, concentrated; Sodium hydroxide; Water for injection

What the medicine looks like and contents of the package:

Wainua is a solution for injection which is clear, colourless to yellow, intended for subcutaneous injection.

Each pack contains 1 single-use pre-filled pen.

Manufacturer: AstraZeneca AB, Södertälje Sweden.

License Holder and importer:

AstraZeneca (Israel) Ltd., 1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 180-02-38025-99

This leaflet was checked and approved by the Ministry of Health in September 2025.

INSTRUCTIONS FOR USE

These instructions for use contain information on how to inject Wainua solution for injection in pre-filled pen.

Read these instructions for use before you first use your pre-filled pen and each time you get a new pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Your healthcare provider should show you or your caregiver how to use the pre-filled pen the right way. If you or your caregiver have any questions, talk to your healthcare provider.

Important information you need to know before using the pen

- Store Wainua pen in a refrigerator between 2°C to 8°C in the original carton until ready to use. If needed, an unopened carton can be stored at room temperature up to 30°C for up to 6 weeks.
- Keep the pen in the carton until ready to use.
- Each pen contains 1 dose and can only be used one time.
- The dose is given only as an injection under the skin (subcutaneous).

Do not use your pen if it has:

- been frozen.
- been dropped, damaged, or appears to be tampered with.
- passed the expiry date (EXP).

Do not share your pen with anyone else.

- Keep your pen and all medicines out of the sight and reach of children.

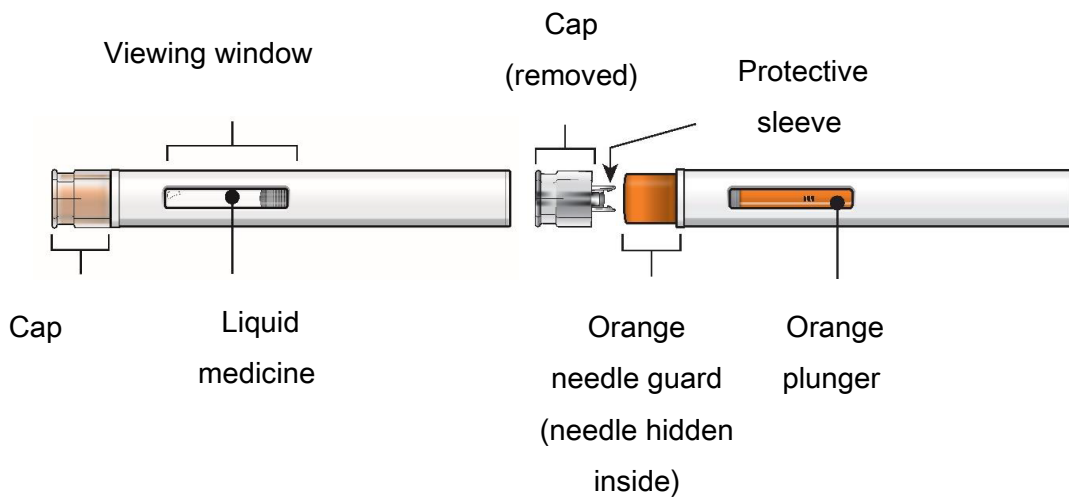
Your pre-filled pen

Do not remove the cap until right before you give the injection.

Do not touch the orange needle guard.

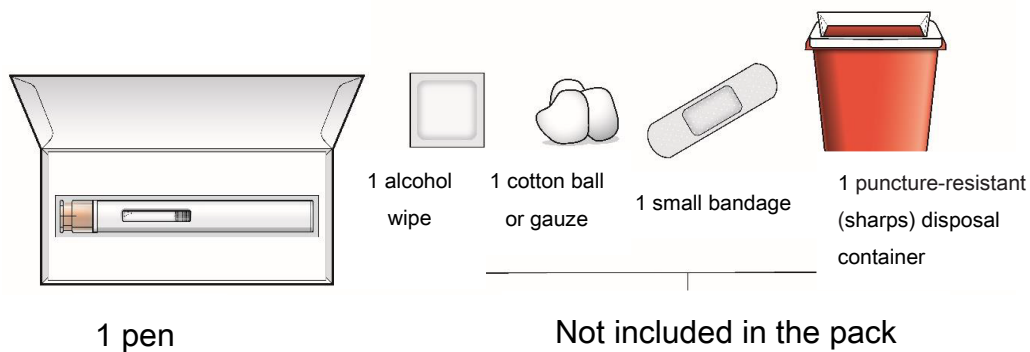
Before use

After use



Preparation for injection

Step 1 – Gather supplies for your injection



Step 2 – Remove from refrigerator and wait 30 minutes

Keep the pre-filled pen in the carton for 30 minutes at room temperature 20°C to 25°C before injecting.



- Do not warm the pen in any other way. For example, do not warm it in a microwave, hot water, or near other heat sources.
- Keep it away from light or direct sunlight.

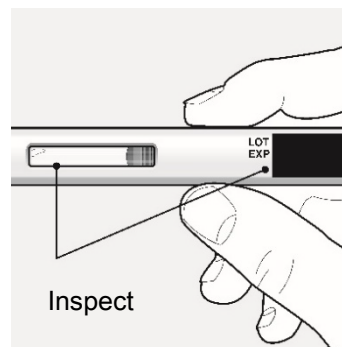
Step 3 – Remove the pre-filled pen from the carton and inspect

Check the pre-filled pen for damage.

Check the expiry (EXP) date.

Check the liquid through the viewing window.

- If you see small air bubbles in the liquid, it is normal.
- The liquid should be clear and colorless to slightly yellow.
- **Do not** use if the liquid is cloudy, discolored, or contains visible particles.



Injecting with your pre-filled pen

Step 4 – Choose an injection site

You or your caregiver can inject in the front of your thigh or the lower part of your stomach (abdomen).

A caregiver or healthcare professional may also inject you in the back of your upper arm.

Do not try to inject yourself in the upper arm.

For each injection, choose an injection site that is at least 3 cm away from where you last injected.

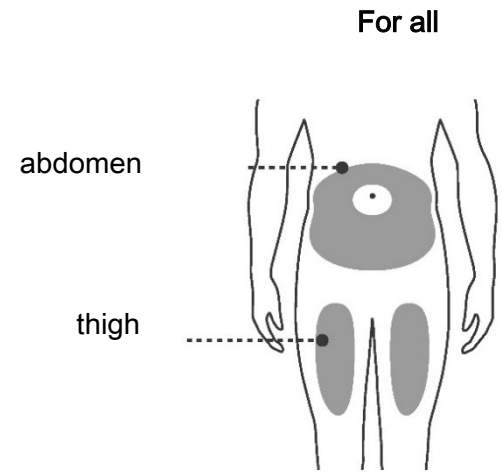
Do not inject:

- into the 5-cm area around your belly button.
- where skin is red, warm, tender, bruised, scaly, or hard.
- into scars, damaged, discolored, or tattooed skin.
- through clothing.

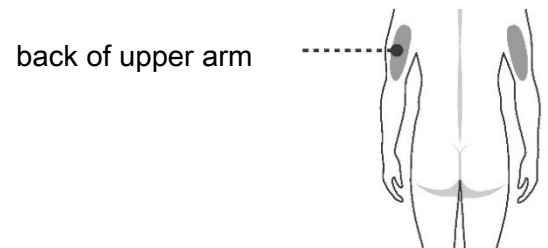
Step 5 – Wash your hands and clean the injection site

Wash your hands well with soap and water.

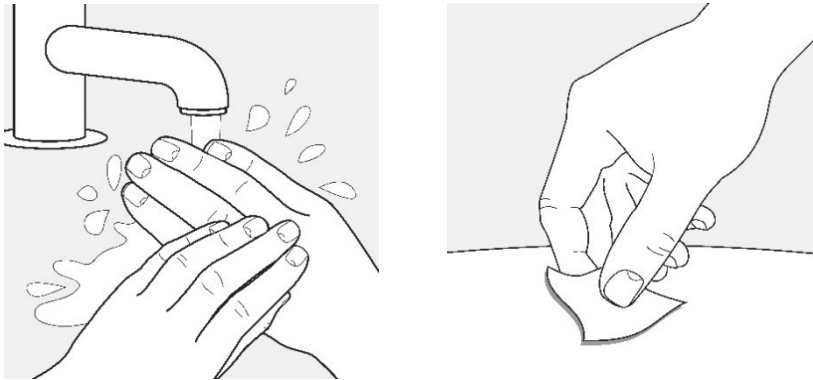
Clean the injection site with an alcohol wipe or with soap and water. Let it air dry.



For caregivers or healthcare professional only



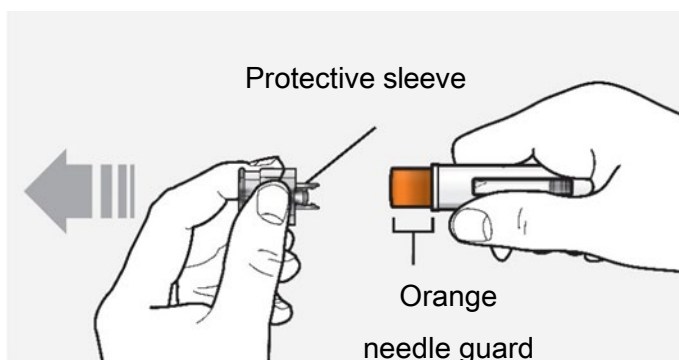
Do not touch the cleaned area before injecting.



Step 6 – Pull off the cap

Hold the pen body with 1 hand and carefully pull the clear cap straight off with your other hand. The orange needle guard is now exposed, and the needle is hidden underneath.

- Throw away the clear cap.
- **Do not** touch the needle or push on the orange needle guard with your finger.
- **Do not** recap the pre-filled pen. This could cause the medicine to come out too soon or damage the pre-filled pen.



Step 7 – Injecting

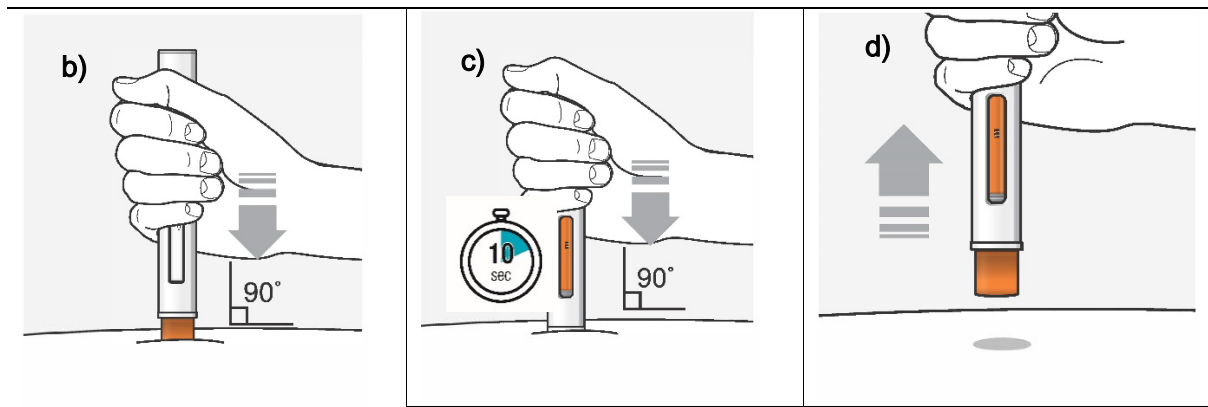
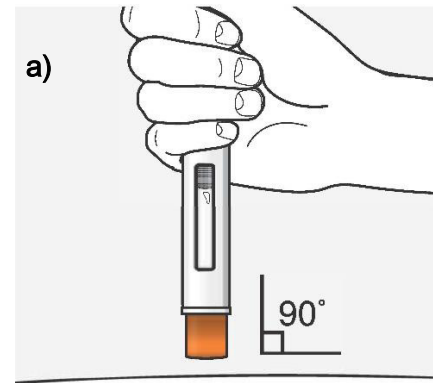
Inject using the pre-filled pen by following the steps in figures **a**, **b**, **c** and **d**.

When injecting, press and hold the pen for 10 seconds until the orange plunger fills the viewing window. You may hear a first ‘click’ at the start of the injection and a second ‘click’ at the end of the injection. This is normal.

Do not move or change the position of the pre-filled pen after the injection has started.

Position the pre-filled pen.

- Place the orange needle guard flat against your skin (90-degree angle).
- Make sure you can see the viewing window.



Press down firmly and hold.

- You may hear the **first ‘click’** right away, this tells you the injection has started.

Hold down firmly for about 10 seconds.

- The orange plunger will fill the viewing window.

After you have completed your injection, lift the pen straight up.

- The orange needle guard will slide down

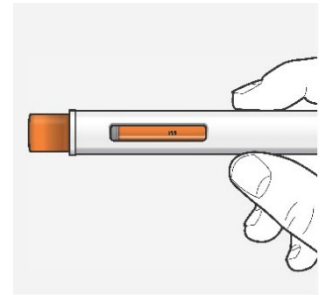
- The orange plunger will move down in the viewing window.
- You may hear the **second 'click'** at the end of injection.
- and lock into place over the needle.

Step 8 – Check the viewing window

Check the viewing window to make sure all the medicine has been injected.

If the orange plunger rod does not fill the viewing window, you may not have received the full dose.

If this happens or if you have any other concerns, contact your doctor or healthcare professional.



Before injection

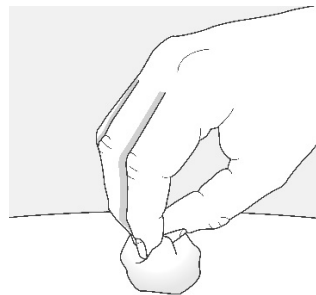


After injection

Step 9 – Check the injection site

There may be a small amount of blood or liquid at the injection site. This is normal.

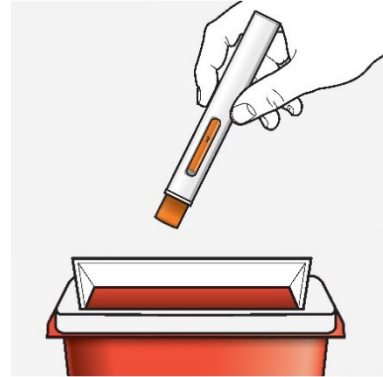
If needed, press a cotton ball or gauze on the area and apply a small bandage.



Step 10 – Throw away the used pre-filled pen

Put your used pen in a **puncture resistant sharps disposal container** right away after use.

Do not throw away the pen in your household waste.



Disposal guidelines

Dispose of the full container as instructed by your healthcare professional or pharmacist.

Do not recycle your used sharps disposal container.