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Wainua

Pronunciation: *way-noo'-ah*
Generic name: Eplontersen
Dosage form: subcutaneous injection (45 mg/0.8 mL)
Drug class: Miscellaneous metabolic agents

Medically reviewed by Melisa Puckey, BPharm. Last updated on Oct 16, 2024.

What is Wainua?

Wainua (eplontersen) is used to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN or ATTRv-PN), which is a rare, progressive disease that can be fatal if not treated. Amyloidosis is a disease caused by a buildup of abnormal proteins called amyloid. Eplontersen works by decreasing the amount of TTR protein that is made, which slows disease progression and improves neuropathy and the patient's quality of life.

Wainua drug class of medications called LICA (ligand-conjugated antisense oligonucleotide). Wainua mechanism of action is by causing the breakdown of mutant and wild-type TTR mRNA by binding to the TTR mRNA, which lowers serum TTR protein and TTR protein deposits in tissues.

Wainua is given as a monthly self-administered subcutaneous injection using an autoinjector.

Wainua FDA approval was granted on December 21, 2023, to AstraZeneca to treat the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Wainua FDA approval came after positive results from the phase III clinical trial NEURO-TTRansform (NCT04136184).

What is ATTR amyloidosis?

ATTR amyloidosis is caused by a protein in the body called transthyretin (TTR) that changes from its normal shape and then forms fibrous clumps. These clumps of misshapen protein are then deposited into various organs and nerves, which can stop the organs and nerves from working properly.

ATTR amyloidosis polyneuropathy (ATTR-PN) is the build-up of amyloid protein in nerves and can cause symptoms such as a loss of sensation, tingling, numbness, or pain in the hands and feet.

ATTR cardiomyopathy (ATTR-CM) is when clumps of amyloid build up in the heart tissue, which affects the heart's ability to work properly, leading to symptoms similar to heart failure and an enlarged heart.

Wainua side effects

Wainua side effects are vomiting (9%), protein in your urine (8%), injection site reactions (7%), blurred vision (6%), cataracts (6%), and decreased vitamin A serum levels (15%) . Low vitamin A level is a serious, but common side effect of treatment with this medicine. Your healthcare provider should tell you to take vitamin A supplements while using eplontersen. Do not take more than the amount of vitamin A your healthcare provider has recommended. Call your healthcare provider if you develop eye problems such as difficulty seeing at night, or in low-lit areas (night blindness), or dry eyes. If you develop eye problems while receiving treatment with this medicine, your healthcare provider should send you to see an eye doctor.

Atrioventricular (AV) heart block is a serious side effect that occurred in 2% of patients in clinical trials.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Wainua side effects (more detail)

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Before taking this medicine

Pregnancy

Tell your healthcare provider if you are pregnant, plan to become pregnant, or think you may be pregnant, as it is not known if Wainua can harm your unborn baby. Changes in vitamin A levels and vitamin A supplementation related to the use of Wainua may harm your unborn baby.

Breastfeeding

Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if Wainua can pass into your breast milk or harm your baby. Talk with your healthcare provider about the best way to feed your baby while you are using this medicine.

Wainua pregnancy and breastfeeding warnings (more detail)

How should I use Wainua?

Read the detailed Instructions for Use that come with your single-dose autoinjector. Your healthcare provider will show you or your caregiver how, where and when to inject it.

If you or your caregiver have any questions, ask your healthcare provider.

Instructions for use

Remove the single-dose autoinjector from the refrigerator 30 minutes prior to the injection and allow it to warm to room temperature. Do not use other warming methods.

Inspect the autoinjector visually for particulate matter and discoloration prior to administration. The solution should appear colorless to yellow. Do not use if cloudiness, particulate matter, or discoloration is observed prior to administration.

Wainua is injected under your skin (subcutaneously) in your stomach area (abdomen), or the front of your upper legs (thighs) by you or a caregiver. A caregiver may also give you an injection in the outer area of your upper arm.

Wainua should be injected 1 time on the same day of each month

For more detailed instructions with diagrams click here Wainua Patient information

If you miss a dose, take the missed dose as soon as possible. Then inject Wainua 1 month from the date of your last dose to get back on a monthly dosing schedule. If you have questions about your schedule, ask your healthcare provider.

Dosing information

Recommended Wainua dose: 45 mg administered by subcutaneous injection once a month.

Wainua is available as a 45 mg/0.8 mL single-dose autoinjector.

Detailed Wainua dosage information

How effective is Wainua?

In the global, open-label, randomized Phase 3 NEURO-TTRansform trial for Wainua in patients with ATTR amyloidosis polyneuropathy (ATTRv-PN) there was an 81.2% reduction in serum transthyretin (TTR) concentration when compared to the baseline, showing that eplontersen reduced TTR protein production.

The study showed eplontersen had a statistically significant effect on the modified Neuropathy Impairment Score +7 (mNIS+7), which is a measure of neuropathic disease progression when compared to the placebo group.

Treatment also significantly improved patient-reported quality of life compared to the external placebo group ($p<0.0001$) as measured by the Norfolk Quality of Life Questionnaire-Diabetic Neuropathy (Norfolk QoL-DN).

Eplontersen is also being studied in the treatment of ATTR cardiomyopathy (ATTR-CM).

Interactions

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Tell your healthcare provider if you take:

- Vitamin A or beta-carotene supplements.

Ask your healthcare provider or pharmacist if you are not sure if you take any of these medicines. Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine. Not all possible interactions are listed here.

Wainua Package Insert

Review the Wainua Package Insert for more detailed information about this medicine. The Wainua PI contains more detail information on Indications and Usage, Dosage and Administration, Clinical Pharmacology, Clinical Studies, Drug Interaction and more. Discuss any medical questions you have with your doctor or other health care provider. This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

The Package Insert is sometimes called Wainua Prescribing Information (PI) or Wainua FDA label.

Ingredients

Active ingredient: eplontersen sodium.

Inactive ingredients: dibasic sodium phosphate, anhydrous; monobasic sodium phosphate, dihydrate; sodium chloride; water for injection, and may include hydrochloric acid and sodium hydroxide for pH adjustment.

Storage

- Store in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton.
- It can also be kept at room temperature that is no higher than 86°F (30°C) in the original carton for up to 6 weeks.
- Do not let the medicine reach temperatures above 86°F (30°C).

- If you do not use an autoinjector kept at room temperature within 6 weeks, throw it away.
- Do not freeze.
- Do not expose this medicine to heat or light.

Company

Wainua AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850 AstraZeneca.

Ionis Pharmaceuticals, Inc.

References

1. Ionis presents positive results from Phase 3 NEURO-TTRansform study at International Symposium on Amyloidosis
2. Food and Drug Administration (FDA) Wainua Product Label

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.