WAINZUA®▼(eplontersen) is indicated for the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 and 2 polyneuropathy.[1]

Access to prescribing information and adverse event reporting statement can be found on the reverse.

WAINZUA®
eplontersen 45 mg
injection for subcutaneous use

Offering patients flexibility with once-monthly WAINZUA® homecare

Patients have the flexibility to either:

- Self-administer in their preferred environment
- Have their caregiver administer in their preferred environment
- Have a nurse administer at home via the Homecare Service

The Homecare Service, provided by HealthNet Homecare, is a patient support service developed and funded by AstraZeneca UK. It is available only to eligible patients at healthcare organisations that have formally signed up to it.

- **Dispensing and home delivery** of medication (including text message delivery reminder service)
- **Clinical waste collection/disposal**
- **At-home device training for patients and/or caregivers wanting to self-administer**

  Up to four face-to-face nurse-led visits. The first visit will always be face-to-face. Subsequent visits can be face-to-face or virtual*
- **Provision of funded associated ancillaries**

  This includes sharps containers with alcohol wipes, cotton balls and small plasters (if required)
- **Nurse administration available for patients not wanting to self-administer**
- **Provision of patient information and support materials†**
- **Patient self-administration competency assessment**
- **Optional annual phlebotomy** from Month 18 following the first dose of WAINZUA

- The **Homecare Service** will be offered free of charge to the NHS to all patients receiving **WAINZUA** in line with the product licence
- The service will be available at any point on the patient's treatment pathway, including **WAINZUA**-naive patients from injection number one
- Patients/caregivers who are deemed confident and competent with self-administration by their HCP do not have to be referred for nurse administration
- Deliveries will be once monthly and contain one dose of **WAINZUA** for the first 6 months. After this, deliveries will be 2 or 3 monthly ongoing thereafter (at Trust discretion)

*Where appropriate and as agreed with the Trust. HealthNet Homecare provide video conferencing via their internal telephony system 3CX, which is secure and UK hosted, but isn't DTAC approved as there was no requirement to do so at the time of commissioning the service. However, 3CX is on HealthNet Homecare's Validation Roadmap.

†In addition to the standard patient information leaflet in the pack.

ATTRv=hereditary transthyretin amyloidosis; DTAC=digital technology assessment criteria for health.

1. WAINZUA® (eplontersen) Summary of Product Characteristics.

AstraZeneca

Nurse-led device training

Patients can be referred to the Homecare Service at any point on their treatment pathway. Patients/caregivers are eligible for up to four face-to-face or virtual nurse-led self administration training visits

Appointment 1

The initial homecare administration training session offers up to 2 hours of dedicated face-to-face support to patients and/or caregivers

Appointment 2–4

The remaining optional training sessions would follow, up to injection four, as required. These sessions provide up to 1 hour of dedicated face-to-face or virtual support to patients and/or caregivers

Should the patient or caregiver be unable to confidently administer WAINZUA, the homecare provider and NHS clinical team will make a collective decision on the best approach. Ongoing nurse administration is available

Storage of WAINZUA[1]

Store in the refrigerator (2°C to 8°C). Do not freeze

WAINZUA may be stored in its original carton at room temperature for up to 6 weeks. If not used within 6 weeks, it should be discarded

Do not expose to heat or let WAINZUA reach temperatures >30°C

For more information or to initiate Homecare Service, speak to your Hospital Homecare Pharmacy Team, or scan the QR code to speak to your AstraZeneca WAINZUA representative

Please scan the QR code to view the full Prescribing Information for WAINZUA

Adverse events should be reported. Reporting forms and information can be found at *www.mhra.gov.uk/yellowcard* or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting *https://contactazmedical.astrazeneca.com* or by calling 0800 783 0033.

1. WAINZUA® (eplontersen) Summary of Product Characteristics.

PRESCRIBING INFORMATION

WAINZUA® ▼ (eplontersen) 45MG SOLUTION FOR INJECTION IN PRE-FILLED PEN

Consult Summary of Product Characteristics (SmPC) before prescribing. **Indication:** For the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv amyloidosis) in adult patients with Stage 1 and 2 polyneuropathy. **Presentation:** Pre-filled pen containing 45mg eplontersen in 0.8mL. **Dosage and Administration:** Treatment should be prescribed and supervised by physicians experienced in the diagnosis and treatment of amyloidosis. The recommended dose is 45mg of eplontersen by subcutaneous injection administered monthly. If a dose is missed, the dose should be administered as soon as possible. Thereafter, the patient can resume dosing at monthly intervals from date of last dose. A patient or their caregiver may administer Wainzua after being trained in subcutaneous injection technique. The pre-filled pen should be removed from refrigerated storage at least 30 minutes before use and allowed to reach room temperature prior to injection. Self-administer as a subcutaneous injection into the upper thigh or abdomen. If a healthcare professional or caregiver administers the injection, the upper arm can also be used. A patient should not self-inject in the arm. It should not be injected into skin which is tender, bruised, erythematous, or hard, into scars or damaged skin or area around the navel area. **Elderly population:** No dosing adjustment is required for patients ≥65 years of age. **Renal impairment:** No dose adjustment is necessary in patients with mild to moderate renal impairment (estimated glomerular filtration rate [eGFR] ≥ 45 to < 90 ml/min/1.73 m2). Eplontersen has not been studied in patients with eGFR <45 ml/min/1.73 m2 or end-stage renal disease and should only be used in these patients if clinical benefit outweighs the potential risk. **Hepatic impairment:** No dosing adjustment is necessary in patient with mild hepatic impairment. Wainzua has not been studied in patients with moderate to severe hepatic impairment, the clinical benefit must outweigh the potential risk if used in these patients. **Patients undergoing liver transplant:** The safety and efficacy of Wainzua in patients undergoing liver transplant has not been established. **Paediatric population:** The safety and efficacy of Wainzua in children and adolescents under 18 years of age has not been established. **Contraindications:** Hypersensitivity to the active substance or excipients. **Warnings and Precautions: Vitamin A deficiency:** Wainzua is expected to reduce serum vitamin A, and any symptoms or signs related to vitamin A deficiency should be evaluated prior to initiation of treatment. Patients receiving Wainzua should take oral supplementation of approximately, but not exceeding, 2 500 IU (female) to 3 000 IU (male) of vitamin A per day to reduce the potential risk of ocular symptoms due to vitamin A deficiency. Vitamin A levels below the lower limit of normal should be corrected. Before initiating treatment with Wainzua exclude pregnancy and advise patients on effective contraception. Discontinue Wainzua and vitamin A supplementation if a women intends to become pregnant, or in the event of an unplanned pregnancy. Due to the long half-life of eplontersen a Vitamin A deficiency may develop after cessation of treatment. No recommendation can be given whether to continue or discontinue vitamin A supplementation during the first trimester of an unplanned pregnancy. **Sodium Content:** Wainzua is considered essentially 'sodium-free'. **Drug Interactions:** Wainzua is not expected to cause or be affected by drug-drug interactions. **Pregnancy and Lactation:** Wainzua should not be used during pregnancy. Wainzua should not be initiated in pregnant women or women intending to become pregnant. There is no data for the use of Wainzua in pregnant women. Wainzua will reduce the plasma levels of vitamin A, which is crucial for normal foetal development. It is not known whether vitamin A supplementation will be sufficient to reduce the risk to the foetus. **Lactation:** A risk to the breastfed child cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from Wainzua therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. **Ability to Drive and Use Machines:** Wainzua has no or negligible influence on the ability to drive and use machines. **Undesirable Events:** Consult SmPC for full list of side effects. **Very Common (≥1/10):** Vitamin A decreased. **Common (≥1/100 to <1/10):** Vomiting, proteinuria, cataracts, injection site reactions (erythema, pain, pruritus).

Legal Category: POM. **Marketing Authorisation Number:** Wainzua 45mg solution for injection in pre-filled pen PLGB 17901/0377 **Presentation & Basic NHS Cost:** Wainzua 45mg solution for injection in pre-filled syringe 1 x single use pre-filled pen: £31,954.12 **Business Responsible for Sale and Supply / Further Information:** AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London, N1C 4AG, UK.

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