

## Package leaflet: Information for the patient

### Wainzua® 45 mg solution for injection in pre-filled pen Eplontersen

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Wainzua is and what it is used for

The active substance of Wainzua is eplontersen, which is a type of medicine called an antisense oligonucleotide inhibitor.

#### What Wainzua is used for

Wainzua is a treatment for adults with polyneuropathy associated with hereditary transthyretin amyloidosis (ATTRv), which runs in families. The illness is caused by problems with a protein called transthyretin (TTR). It is made mostly in the liver and carries vitamin A and other substances around the body.

In people with this illness, small fibres of TTR protein clump together to make deposits called 'amyloid'. Amyloid can build up around or within the nerves, heart and other places in the body, stopping them from working normally. This widespread nerve damage causes the symptoms of the illness including progressive weakness and loss of sensation in the legs and arms, as well as dizziness, diarrhoea and constipation.

#### How Wainzua works

Wainzua 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. That can help to reduce the effects of the illness.

#### 2. What you need to know before you use Wainzua

### **Do not use Wainzua if:**

- You are allergic to eplontersen or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

#### **You will need vitamin A supplements.**

Treatment with Wainzua lowers the amount of vitamin A in your blood. Your doctor will measure your vitamin A levels before treatment.

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

**Signs of low vitamin A can include poor vision** especially at night, dry eyes, hazy or cloudy vision.

- **Talk to your doctor if you notice problems with vision** or any other eye problems while using Wainzua. 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 Wainzua. Vitamin A levels affect the development of an unborn child. Women of child-bearing age **must practise effective contraception** during treatment (see section “Pregnancy, breast-feeding and contraception” below).

- **Tell your doctor if you are planning to become pregnant.** Your doctor will tell you to stop taking Wainzua and vitamin A supplementation. Your doctor will also ensure that your vitamin A levels have returned to normal before attempting to get pregnant.
- **Tell your doctor if you have an unplanned pregnancy.** Your doctor will tell you to stop taking Wainzua. 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**

Wainzua is not recommended in children and adolescents under 18 years of age.

### **Other medicines and Wainzua**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

### **Pregnancy, breast-feeding and contraception**

If you are pregnant or breastfeeding, think you may be pregnant, or are trying to become pregnant ask your doctor or pharmacist for advice before using this medicine.

#### **Women of childbearing age**

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

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

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

#### Pregnancy

You should not use Wainzua if you are pregnant.

#### Breast-feeding

It is not known whether the active substance of Wainzua can pass into breast milk. A risk to 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 Wainzua.

#### **Driving and using machines**

It is unlikely that Wainzua will affect your ability to drive and use machines. Your doctor will tell you whether your condition allows you to drive vehicles and use machines safely.

#### **Wainzua contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose of 0.8 ml, that is to say essentially 'sodium-free'.

### **3. How to use Wainzua**

Always use Wainzua exactly as your doctor, pharmacist, or nurse has told you. Check with your doctor, nurse, or pharmacist if you are not sure.

Wainzua is given as an injection under the skin (subcutaneously). The injection can be done in the stomach (abdomen), thigh or, if given by a carer, in the back of your upper arm.

You and your doctor or nurse should decide if Wainzua should be injected by yourself or by your carer. 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 it.

**The recommended dose** of Wainzua is one injection of 45 mg every month.

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

#### **If you use more Wainzua than you should**

If you inject too much, get medical advice immediately, or go to a hospital emergency department. Do this even if you have no symptoms. Bring the medicine's carton or pen with you.

#### **If you forget to use Wainzua**

If you miss your dose of Wainzua, have your next dose as soon as possible and continue your monthly injections from that date on.

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

### **4. Possible side effects**

Like all medicines, Wainzua can have side effects, although not everybody gets them.

**Very common** (may affect more than 1 in 10 people)

- Effects seen in blood tests: low vitamin A (for signs of low vitamin A see section “Warnings and precaution” earlier in this leaflet).

**Common** (may affect up to 1 in 10 people)

- Vomiting.
- Redness, itching, pain where the injection was given.
- Proteinuria.
- Cataracts.

### **Reporting of side effects**

If you get any side effects, **talk to your doctor, pharmacist or nurse**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Wainzua**

Keep this medicine out of the sight and reach of children.

Do not use Wainzua after the expiry date which is stated on the pre-filled pen label and carton after ‘EXP’. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Store in the original package to protect from light.

Do not freeze. Do not expose to heat.

Wainzua may be stored unrefrigerated (below 30°C) in the original carton for up to 6 weeks. If not used within 6 weeks unrefrigerated, it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Wainzua contains**

The active substance is eplontersen. One pre-filled pen contains 45 mg eplontersen (as eplontersen sodium) in 0.8 ml solution.

The other ingredients are sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate anhydrous, sodium chloride and water for injections. Hydrochloric acid and sodium hydroxide may be used to adjust the pH (see “Wainzua contains sodium” in section 2).

### **What Wainzua looks like and contents of the pack**

Wainzua is a solution for injection which is clear, colourless to yellow.

Wainzua is available in a pack containing 1 single-use pre-filled pen.

## **Marketing Authorisation Holder**

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## **Manufacturer**

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## **Other sources of information**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

### **Product name Reference number**

Eplontersen 45 mg solution for injection in pre-filled pen 17901/0377

This is a service provided by the Royal National Institute of the Blind.