

ONPATTRO[®]▼

2 mg/mL concentrate for solution for infusion (patisiran)

Educational Material for patients for safe use of Onpattro in the home

Read all of this information carefully

DO NOT DISCARD

18 December 2020 (date of MHRA approval)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Tell your doctor or nurse straight away if you get any side effects after receiving Onpattro.

You can also report side effects to:

Alnylam: Alnylam UK Ltd. Tel: 08001412569 (+44 1628 878592)

medinfo@alnylam.com

National reporting system: Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store

Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm. By reporting side effects, you can help provide more information on the safety of this medicine.

Table of Contents

1. Introduction	3
2. How is an infusion of Onpattro given?	3
3. What are the signs or symptoms of IRRs?	3
4. What should you do if you experience IRRs	4

This document concerning the administration of Onpattro® has been created in accordance with ordinance included in the marketing authorisation. Additional risk minimisation measures beyond routine measures have been stipulated in the marketing authorisation of the product, in order to ensure the safe and sustainable administration of Onpattro in the home setting, minimizing the risk of Infusion Related Reactions (IRRs) and to increase the benefit-risk ratio of Onpattro. This document is therefore, an integral and mandatory part of the marketing authorisation to ensure health care professionals who prescribe Onpattro and patients are aware of the special safety requirements and that they take these into consideration.

1. Introduction

Your doctor prescribed Onpattro for you. A doctor or a nurse has administered it to you in the clinic. As you have now received at least 3 infusions and you did not have problems with your Onpattro infusions in the clinic, your doctor has arranged for a nurse or doctor to administer your infusion at home.

This document complements the package leaflet that your doctor or nurse will give you and is intended to answer your questions about receiving Onpattro at home, to inform you of the risk of Infusion Related Reactions (IRRs) with Onpattro and what you should do if you experience IRRs. Please ask your doctor or nurse, if you have any further questions on the use of Onpattro.

2. How is an infusion of Onpattro given?

Onpattro will be given in the same way at home as you previously received the infusion in the clinic.

Onpattro is given as a drip into a vein in your arm (called an 'intravenous [IV] infusion'). If you have a central venous catheter, you may receive the infusion through the catheter. The infusion is usually given over about 80 minutes.

IRRs may happen during treatment with Onpattro. Before each infusion, you will be given medicines that help to lower the chance of an IRR. These medications include:

- anti-histamines (an anti-allergy medicine)
- a corticosteroid (an anti-inflammatory medicine)
- a pain reliever (a medicine that reduces pain or fever)

These medications are given 60 minutes before the start of the infusion of Onpattro by the doctor or nurse.

After you have received these medications, the doctor or nurse will administer Onpattro to you in the same way you have received it in the clinic. The doctor or nurse will monitor you before, during and after the infusion for any IRRs or other side effects.

3. What are the signs or symptoms of IRRs?

IRRs are very common, meaning that they affect more than 1 in 10 people who receive Onpattro.

Tell the doctor or nurse straight away if you get any of the following signs of an infusion-related reaction or other symptoms during an infusion of Onpattro.

- Stomach pain
- Feeling sick (nausea)

- Body aches or pain, including pain in the back, neck, or joints
- Headache
- Feeling tired (fatigue)
- Chills
- Dizziness
- Cough, feeling short of breath, or other breathing problems
- Reddening of the face or body (flushing), skin warm, rash or itching
- Chest discomfort or chest pain
- Rapid heart rate
- Low or high blood pressure; some patients have fainted during the infusion due to low blood pressure
- Pain, redness, burning sensation, or swelling at or near the infusion site
- Swelling of the face

If you have an IRR, the doctor or nurse may slow down or stop your infusion and may give you other medicines to treat the symptoms. The medications may include additional doses of the medications given before the infusion (anti-histamines, corticosteroids or pain reliever), fluids into your vein, or other medication as needed for symptoms.

When these reactions stop, or get better, the doctor or nurse may decide to start the infusion again. Your doctor may ask you to return to the clinic to receive future infusions.

4. What should you do if you experience IRRs

Tell your doctor or nurse **immediately** if you experience any of the signs or symptoms of IRRs or other side effects during treatment with Onpattro.

If you experience an IRR after the nurse has left the home call the number provided to you by your doctor or nurse, which may also be entered below for reference.

Name:

Tel: _____

In case of an emergency, call 999 immediately.