waylivra®▼
(volanesorsen) injection 285 mg/1.5 mL
▼This medicinal product is subject to additional monitoring.

Important risk minimisation information for patients and their carers

WAYLIVRA® ▼(volanesorsen sodium)

Patient and Carer Guide

Introduction

You have been diagnosed with familial chylomicronemia syndrome (FCS) and your specialist doctor has prescribed WAYLIVRA. This educational material includes information about a potentially serious side effect called thrombocytopenia. It is important to immediately report any symptoms of this side effect to your specialist doctor. Be sure to read this entire guide and note that this document does not take the place of talking to your specialist doctor about your medical condition or your treatment.

What is the most important information I should know about WAYLIVRA?

- **WAYLIVRA can cause serious side effects, including decreased number of platelets in the blood.** Platelets help the blood to clot and stop bleeding. If platelet levels fall, then you may be more likely to bleed after minor injury and you may have an increased risk of bleeding without obvious injury when platelets fall too low. **Thrombocytopenia** occurs when the number of platelets in the blood falls below the lower limit of normal. Your specialist doctor will order a simple blood test to determine your platelet count before you start taking WAYLIVRA and then at least every 2 weeks thereafter. If you have moderate to severe thrombocytopenia, your specialist doctor will inform you not to take WAYLIVRA.

- **Will I need to be monitored while on treatment?**
  When you are being treated with WAYLIVRA, your specialist doctor will closely monitor you for any unwanted changes in your platelet count and may change how often you take WAYLIVRA, including the possibility of interrupting or discontinuing your treatment or increasing the frequency of your blood tests. **It is important that you follow your specialist doctor's platelet monitoring and treatment instructions to prevent severe thrombocytopenia and reduce the risk of bleeding.**

- **After starting WAYLIVRA, it is important to tell your specialist doctor right away if you develop any signs of low platelet count such as:**
  - Pinpoint, round, red, purple, or brown spots on the skin
  - Unexpected bruising
  - Blood in the white part of the eye
  - Other unusual bleeding, such as nosebleeds, bleeding from gums, bloody bowel movements, or unusually heavy menstrual bleeding (periods)
  - Any prolonged bleeding
  - Neck stiffness
  - Unusually severe headache

- **If you see a healthcare professional who is not your usual specialist doctor you should inform them that you are taking WAYLIVRA.** This is particularly important if this is in connection with symptoms of a low platelet count (thrombocytopenia).

WAYLIVRA® Product Registry

A European registry study of patients with FCS receiving WAYLIVRA treatment is being conducted. **Your participation in this registry is encouraged** as it will help improve the understanding of thrombocytopenia and the risk of bleeding associated with WAYLIVRA treatment as well as the long-term safety of WAYLIVRA treatment. Information on how to enroll in the registry study can be obtained from your specialist doctor.

Reporting of side effects

Thrombocytopenia is not the only possible side effect of WAYLIVRA. Please consult the Patient Information Leaflet (PIL) in the product package for other side effects and additional important information or speak to your specialist doctor or nurse. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this guide and PIL. You can also report side effects directly via:

Ireland HPRA Pharmacovigilance

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

United Kingdom

Yellow Card Scheme

Tel: 0800 731 6789

Website: www.mhra.gov.uk/yellowcard

E-mail: yellowcard@mhra.gsi.gov.uk

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.

WAYLIVRA is distributed by Sobi Ltd on behalf of Akcea Therapeutics Ireland Limited the Marketing Authorisation Holder for WAYLIVRA in the United Kingdom.

If you would like any further information on WAYLIVRA please contact:
Tel: +44 (0) 800 111 4754
Email: medical.info.uk@sobi.com

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