

**Medication Guide KYNAMRO®** (kye-NAM-roe)  
(mipomersen sodium)  
Injection

**What is the most important information I should know about KYNAMRO?**

- KYNAMRO is available only through certified pharmacies that are enrolled in the KYNAMRO REMS Program. Your doctor must be enrolled in the program in order for you to be prescribed KYNAMRO.

**KYNAMRO may cause serious side effects, including liver problems. KYNAMRO can cause liver problems such as increased liver enzymes or increased fat in the liver.**

- Your doctor should do blood tests to check your liver before you start KYNAMRO and during your treatment. If your tests show some liver problems, your doctor may stop KYNAMRO.
- Tell your doctor if you have had liver problems, including liver problems while taking other medicines.
- Tell your doctor right away if you have any of these symptoms of liver problems while taking KYNAMRO:
  - nausea
  - vomiting
  - fever
  - loss of appetite
  - you are more tired than usual
  - yellowing of your eyes or skin
  - dark urine
  - itching
  - stomach pain that gets worse, does not go away, or changes
- Drinking alcohol may increase your chance of having liver problems or make your liver problems worse. You should not have more than 1 alcoholic drink each day while using KYNAMRO.

**What is KYNAMRO?**

KYNAMRO is a prescription medicine used along with diet and other lipid-lowering treatments in people with homozygous familial hypercholesterolemia (HoFH) to reduce:

- LDL (“bad”) cholesterol
- total cholesterol
- a protein that carries “bad” cholesterol in the blood (apolipoprotein B)
- non-high-density lipoprotein cholesterol (non-HDL-C)

It is not known if KYNAMRO can decrease problems from high cholesterol, such as heart attack, stroke, death or other health problems.

It is not known if KYNAMRO is safe and effective in people with high cholesterol but who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

It is not known if KYNAMRO is safe and effective as an additional treatment to LDL-apheresis.

It is not known if KYNAMRO is safe and effective in people with kidney and liver problems, including people who are on kidney dialysis.

It is not known if KYNAMRO is safe and effective when used in children under the age of 18.

### **Who should not take KYNAMRO?**

#### **Do not take KYNAMRO if you:**

- have moderate or severe liver problems or active liver disease, including people who have unexplained abnormal liver tests.
- are allergic to mipomersen or any of the ingredients in KYNAMRO. See the end of this leaflet for a complete list of ingredients in KYNAMRO.

### **What should I tell my doctor before taking KYNAMRO?**

Before you take KYNAMRO, tell your doctor if you:

- have liver problems
- have kidney problems
- drink alcohol
- are pregnant or plan to become pregnant. KYNAMRO may cause harm to your unborn baby. If you are a female who can get pregnant, you should use effective birth control while using KYNAMRO. Talk with your doctor to find the best method of birth control for you. If you become pregnant while taking KYNAMRO, stop taking KYNAMRO and call your doctor right away.
- are breastfeeding or plan to breastfeed. It is not known if KYNAMRO passes into your breast milk. You and your doctor should decide if you will use KYNAMRO or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Before starting a new medicine while taking KYNAMRO, even if you will only be taking it for a short time, ask your doctor or pharmacist if it is safe to take while you are using KYNAMRO.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

### **How should I take KYNAMRO?**

- See the **Instructions for Use** that comes with this Medication Guide for complete information on how to use KYNAMRO.
- KYNAMRO is given by injection under your skin (subcutaneous) 1 time each week. KYNAMRO is available in single-use (1 time) pre-filled syringe.
- Take KYNAMRO exactly as your doctor tells you to take it.
- Make sure that you are or your caregiver is trained by your doctor or other healthcare provider on how to inject KYNAMRO the right way.
- Do not try to give yourself or have another person give you injections at home until you or both of you understand and are comfortable with how to prepare for your dose and give the injection.
- Take KYNAMRO on the same day of the week at the same time of day.
- If you miss a dose or forget to take your dose of KYNAMRO at your usual weekly time, you can take it when you remember, unless it is less than 3 days until your next weekly dose. If it is less than 3 days until your next weekly dose, wait and take your next weekly dose at your regularly scheduled time. Do not take a double dose at the same time to make up for a forgotten or missed dose.
- It is important that KYNAMRO is at room temperature when it is injected.
- Do not mix KYNAMRO with other injectable medicines.
- Do not use KYNAMRO at the same time as other injectable medicines.
- If you use too much KYNAMRO, call your doctor right away.
- **Do not** stop taking KYNAMRO without talking to your doctor.

### **What are the possible side effects of KYNAMRO?**

**KYNAMRO can cause serious side effects, including:**

- See **“What is the most important information I should know about KYNAMRO?”**
- **injection site problems.** Skin reactions can happen in some people including redness or discoloration of the skin, pain, tenderness, itching, and swelling around the injection site. You may also get a reaction at a former site of injection, when injecting at a different site, or after an injury to an injection site.
- **flu-like symptoms,** including fever, chills, aches, and tiredness. These symptoms usually happen within 2 days of an injection.

**Call your doctor right away if you have any of the serious side effects of KYNAMRO.**

**The most common side effects of KYNAMRO include:**

- injection site problems
- flu-like symptoms
- nausea
- headache

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects of KYNAMRO. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store KYNAMRO?**

- Store KYNAMRO in a refrigerator between 36°F to 46°F (2°C to 8°C). If a refrigerator is not available, KYNAMRO may be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 14 days if it is kept away from heat.
- Protect KYNAMRO from light and store in the original carton.
- Safely throw away medicine that is out of date or no longer needed.

**Keep KYNAMRO and all medicines out of the reach of children.**

**General information about the safe and effective use of KYNAMRO**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use KYNAMRO for a condition for which it was not prescribed. Do not give KYNAMRO to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about KYNAMRO. You can ask your pharmacist or doctor for information about KYNAMRO that is written for healthcare professionals.

For more information, go to [www.KYNAMRO.com](http://www.KYNAMRO.com) or call 1-877-KYNAMRO (1-877-596-2676).

**What are the ingredients in KYNAMRO?**

**Active ingredient:** mipomersen sodium

**Inactive ingredients:** sterile water, hydrochloric acid, and sodium hydroxide

This Medication Guide has been approved by the U.S. Food and Drug Administration.

**KYNAMRO is manufactured for:**

Genzyme Corporation  
500 Kendall Street  
Cambridge, MA 02142

KYNAMRO is a registered trademark of Genzyme Corporation.

Issued: May 2016