

**Patient Information**  
**LIPTRUZET™ (LIP-true-zett)**  
**(ezetimibe and atorvastatin)**  
**Tablets**

Generic name: ezetimibe and atorvastatin tablets

Read this information carefully before you start taking LIPTRUZET™ and each time you get more LIPTRUZET. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about LIPTRUZET, ask your doctor. Only your doctor can determine if LIPTRUZET is right for you.

**What is LIPTRUZET?**

LIPTRUZET contains 2 cholesterol-lowering medications, ezetimibe and atorvastatin.

LIPTRUZET is a prescription medicine used to lower levels of total cholesterol, LDL (bad) cholesterol and fatty substances called triglycerides in the blood. In addition, LIPTRUZET raises levels of HDL (good) cholesterol. LIPTRUZET is for patients who cannot control their cholesterol levels by diet and exercise alone. You should stay on a cholesterol-lowering diet while taking this medicine.

LIPTRUZET has not been shown to reduce heart attacks or strokes more than atorvastatin alone.

It is not known if LIPTRUZET is safe and effective in children.

**Who should not take LIPTRUZET?**

**Do not take LIPTRUZET if you:**

- have active liver problems or repeated blood tests showing possible liver problems.
- are allergic to ezetimibe or atorvastatin or any of the ingredients in LIPTRUZET. See the end of this leaflet for a complete list of ingredients in LIPTRUZET.
- are pregnant or plan to become pregnant. LIPTRUZET may harm your unborn baby. If you are a woman of childbearing age, you should use an effective method of birth control while taking LIPTRUZET. Stop taking LIPTRUZET and call your doctor right away if you get pregnant while taking LIPTRUZET.
- are breastfeeding or plan to breastfeed. LIPTRUZET can pass into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take LIPTRUZET. Do not breastfeed while taking LIPTRUZET.

**What should I tell my doctor before taking LIPTRUZET?**

**Before you take LIPTRUZET, tell your doctor if you:**

- have a thyroid problem
- have kidney problems
- have diabetes
- have unexplained muscle aches or weakness
- drink more than 2 glasses of alcohol daily or have or have had liver problems
- have any other medical conditions

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking LIPTRUZET with certain other medicines or substances can increase the risk of muscle problems or other side effects.

Especially tell your doctor if you take medicines for:

- your immune system
- cholesterol
- infections
- birth control
- heart failure
- HIV or AIDS
- hepatitis C
- gout

Also tell your doctor if you drink large amounts of grapefruit juice.

### **How should I take LIPTRUZET?**

- Take LIPTRUZET exactly as your doctor tells you to take it.
- Your doctor will tell you how much LIPTRUZET to take and when to take it.
- Your doctor may change your dose if needed.
- Do not open your LIPTRUZET pouch until you are ready to take LIPTRUZET.
- Take LIPTRUZET 1 time each day, with or without food. It may be easier to remember to take your dose if you do it at the same time every day, such as with breakfast, dinner, or at bedtime.
- Tablets should be swallowed whole. Do not crush, dissolve, or chew tablets.
- Keep taking LIPTRUZET unless your doctor tells you to stop. If you stop taking LIPTRUZET, your cholesterol may rise again.
- If you miss a dose, do not take an extra dose. Just resume your usual schedule.
- If you take too much LIPTRUZET, call your doctor or Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- See your doctor regularly to check your cholesterol level and to check for side effects. Your doctor may do blood tests to check your liver before you start taking LIPTRUZET and during treatment.

### **What should I avoid while taking LIPTRUZET?**

- Do not start any new medicines before talking to your doctor. This includes prescription and non-prescription medicines, vitamins, and herbal supplements. LIPTRUZET and certain other medicines can interact causing serious side effects.
- Do not drink more than 2 glasses of alcohol daily.
- Do not get pregnant. If you get pregnant, stop taking LIPTRUZET right away and call your doctor.

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

**LIPTRUZET may cause serious side effects, including:**

- **muscle problems.** LIPTRUZET can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with LIPTRUZET.

**Tell your doctor right away if:**

- **you have unexplained muscle pain, tenderness, or weakness, especially if you have a fever or feel more tired than usual, while you take LIPTRUZET.**
- you have muscle problems that do not go away even after your doctor has advised you to stop taking LIPTRUZET. Your doctor may do further tests to diagnose the cause of your muscle problems.

- **liver problems.** Your doctor should do blood tests to check your liver before you start taking LIPTRUZET and if you have symptoms of liver problems while you take LIPTRUZET. Call your doctor right away if you have the following symptoms of liver problems:
  - feel tired or weak
  - loss of appetite
  - upper belly pain
  - dark urine
  - yellowing of your skin or the whites of your eyes

Also call your doctor right away if you have:

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away
- nausea and vomiting
- passing brown or dark-colored urine
- you feel more tired than usual
- stomach pain
- allergic skin reactions

The most common side effects of LIPTRUZET include:

- muscle and body pain
- changes in your liver function tests

Additional side effects that have been reported in people taking LIPTRUZET, ezetimibe or atorvastatin in clinical studies or general use include: joint pain; diarrhea; tendon problems; memory loss; confusion; depression.

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

These are not all the possible side effects of LIPTRUZET. 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 LIPTRUZET?**

- Store LIPTRUZET at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep LIPTRUZET in the foil pouch until you are ready to take it.
- After you remove a LIPTRUZET tablet from the blister card, slide the blister card back into the case (where a case is provided) and store in a dry place.
- Write down the date the foil pouch was opened in the space provided.
- Keep LIPTRUZET tablets dry and out of the light.
- Safely throw away unused LIPTRUZET tablets **30 days** after the foil pouch is opened.

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

### **General information about the safe and effective use of LIPTRUZET.**

LIPTRUZET may help to reduce your cholesterol in 2 ways. It reduces the cholesterol absorbed in your digestive tract, as well as the cholesterol your body makes by itself. LIPTRUZET does not help you lose weight.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use LIPTRUZET for a condition for which it was not prescribed. Do not give LIPTRUZET to other people, even if they have the same problem that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about LIPTRUZET. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about LIPTRUZET that is written for health professionals.

For more information, go to [www.LIPTRUZET.com](http://www.LIPTRUZET.com) or call 1-800-672-6372.

### **What are the ingredients in LIPTRUZET?**


**Active ingredients:** ezetimibe and atorvastatin

**Inactive ingredients:** lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, magnesium stearate, lactose anhydrous, hydroxypropyl cellulose, sodium bicarbonate. The tablet film coating contains the following inactive ingredients: hydroxypropyl cellulose, hypromellose, titanium dioxide, and carnauba wax

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This Patient Information has been approved by the U.S. Food and Drug Administration

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 Merck Sharp & Dohme Corp., a subsidiary of  
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