

**Patient Information**  
**ROSZET (ROS-zett)**  
(rosuvastatin and ezetimibe)  
tablets, for oral use

**What is ROSZET?**

ROSZET contains two medicines, rosuvastatin and ezetimibe, to lower cholesterol. ROSZET is used:

- Along with diet in adults with high blood cholesterol levels to reduce low density lipoprotein cholesterol (LDL-C) or bad cholesterol.
- Alone or together with other LDL-lowering medicines in adults with a type of high cholesterol called homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

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

**Do not take ROSZET if you:**

- have liver problems or repeated blood tests showing possible liver problems.
- are allergic to ezetimibe or rosuvastatin or any of the ingredients in ROSZET. See the end of this leaflet for complete list of ingredients in ROSZET.

**Before you take ROSZET, tell your healthcare provider about all of your medical conditions, including if you:**

- have unexplained muscle aches or weakness.
- have thyroid problems.
- have kidney problems.
- drink more than 2 glasses of alcohol daily or have had liver problems.
- have diabetes.
- are pregnant or plan to become pregnant. ROSZET may harm your unborn baby. If you become pregnant, stop taking ROSZET and call your healthcare provider right away.
- are breast feeding. ROSZET can pass into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take ROSZET. Do not breastfeed while taking ROSZET.
- are 65 years of age or older.
- are of Asian descent.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Talk to your healthcare provider before you start taking any new medicines.

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

Especially tell your healthcare provider if you take medicines for:

- heartburn (such as antacids that contain aluminum and magnesium hydroxide)
- your immune system (such as cyclosporine)
- cholesterol (such as niacin or nicotinic acid, gemfibrozil, fibrates)
- infections or anti-fungals (such as itraconazole, ketoconazole, and fluconazole)
- heart failure including coumarin anticoagulants (such as warfarin)
- gout (such as colchicine)
- darolutamide (a medicine for the treatment of prostate cancer)
- regorafenib (a medicine used to treat cancer of the colon and rectum)
- anti-viral medicines including certain HIV or hepatitis C virus drugs such as:
  - lopinavir, ritonavir, fosamprenavir, tipranavir, atazanavir, simeprevir
  - combination of
    - sofosbuvir/velpatasvir/voxilaprevir
    - dasabuvir/ombitasvir/paritaprevir/ritonavir
    - elbasvir/grazoprevir
    - sofosbuvir/velpatasvir
    - glecaprevir/pibrentasvir **and**
  - all other combinations with ledipasvir including ledipasvir/sofosbuvir

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure. Know all of the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get new medicine.

**How should I take ROSZET?**

- Take ROSZET exactly as your healthcare provider tells you to take it.
- Take ROSZET 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 ROSZET unless your healthcare provider tells you to stop. If you stop taking ROSZET, your cholesterol may rise again.
- If you miss a dose, do not take an extra dose. Take the next dose at the usual time. **Do not take 2 doses of ROSZET within 12 hours of each other.**

- If you take too much ROSZET, call the Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- See your healthcare provider regularly to check your cholesterol level and to check for side effects. Your healthcare provider may do blood tests to check your liver before you start taking ROSZET and during treatment.

**What are the possible side effects of ROSZET?**

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

- **Allergic reactions, including a severe reaction known as anaphylaxis.** Tell your healthcare provider right away if you have any of the following symptoms:
  - swelling of the face, lips, tongue, and/or throat which makes it difficult to swallow or breathe
  - breathing problems or wheezing
  - feeling dizzy or fainting
  - rash or hives
  - itching

- **Muscle pain, tenderness and weakness (myopathy). Muscle problems,** including muscle breakdown, can be serious in some people and rarely causes kidney damage that can lead to death. You have a higher chance for muscle problems if you are taking certain other medicines with ROSZET. **Tell your healthcare provider 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 ROSZET.**
- you have muscle problems that do not go away even after your healthcare provider has advised you to stop taking ROSZET. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take ROSZET (**see “Especially tell your healthcare provider if you take medicines”**)
- are 65 years of age or older
- are of Asian descent
- have thyroid problems (hypothyroidism) that are not controlled
- have kidney problems
- are taking higher doses of ROSZET

- **Liver problems.** Your healthcare provider may do blood tests to check your liver before you start taking ROSZET and if you have symptoms of liver problems while you take ROSZET. Call your healthcare provider 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 |                    |

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

- |                            |                |                              |
|----------------------------|----------------|------------------------------|
| ○ headache                 | ○ nausea       | ○ muscle aches and pains     |
| ○ weakness                 | ○ constipation | ○ common cold and flu        |
| ○ diarrhea                 | ○ joint pain   | ○ runny nose and sore throat |
| ○ dizziness                | ○ stomach pain | ○ tiredness                  |
| ○ pain (back, hands, legs) |                |                              |

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

These are not all the possible side effects of ROSZET.

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 ROSZET?**

- Store ROSZET at room temperature between 68°F to 77°F (20°C to 25°C).
- **Protect ROSZET bottle from moisture or humidity.**
- **Remove a tablet from bottle only when you are ready to take it.**
- Replace the cap on the bottle and close it tightly after removing the tablet from the bottle.
- After opening the bottle, use the tablets within 30 days.

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

**General information about the safe and effective use of ROSZET.**

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use ROSZET for a condition for which it was not prescribed. Do not give ROSZET to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ROSZET that is written for health professionals.

**What are the ingredients in ROSZET?**

**Active ingredients:** ezetimibe and rosuvastatin

**Inactive ingredients:**

Pregelatinized starch, microcrystalline cellulose, meglumine, dibasic calcium phosphate dihydrate, croscopovidone, colloidal silicon dioxide, sodium stearyl fumarate, mannitol, sodium lauryl sulfate, croscarmellose sodium, povidone, ferric oxide, and magnesium stearate. In addition, the tablet film coating contains the following inactive ingredients: hypromellose,

titanium dioxide, polyethylene glycol and ferric oxide.

**Manufactured by:**

Piramal Pharma Limited,  
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**Manufactured for:**

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For more information, go to [www.ROSZETRX.com](http://www.ROSZETRX.com)

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

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