



Patient Information
ASPRUZYO Sprinkle
(as-PROO-zee-oh spring-KUHL)
(ranolazine)
extended-release granules

What is ASPRUZYO Sprinkle?

ASPRUZYO Sprinkle is a prescription medicine used to treat angina that keeps coming back (chronic angina).

ASPRUZYO Sprinkle may be used with other medicines that are used for heart problems and blood pressure control.

It is not known if ASPRUZYO Sprinkle is safe and effective in children.

Do not take ASPRUZYO Sprinkle if :

- you take any of the following medicines:
 - for fungus infection: ketoconazole, itraconazole
 - for infection: clarithromycin
 - for depression: nefazodone
 - for HIV: nelfinavir, ritonavir, indinavir saquinavir
 - for tuberculosis (TB): rifampin, rifabutin, rifapentine
 - for seizures: phenobarbital, phenytoin, and carbamazepine
 - St. John's wort
- you have scarring of your liver (liver cirrhosis)

Before taking ASPRUZYO Sprinkle, tell your healthcare provider about all of your medical conditions, including if you:

- have or have a family history of a heart problem, called 'QT prolongation' or 'long QT syndrome'
- have liver problems
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if ASPRUZYO Sprinkle will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ranolazine passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ASPRUZYO Sprinkle may affect the way

other medicines work and other medicines may affect how ASPRUZYO Sprinkle works.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take ASPRUZYO Sprinkle?

- Take ASPRUZYO Sprinkle exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much ASPRUZYO Sprinkle to take and when to take it. Do not change your dose unless your healthcare provider tells you to.
- Tell your healthcare provider if you still have symptoms of angina after starting ASPRUZYO Sprinkle.
- Take ASPRUZYO Sprinkle 2 times a day.
- ASPRUZYO Sprinkle may be taken or given as follows:

To open the sachet fold back on dotted line and tear at notch or use scissors.



Directions for use with soft food (e.g., applesauce and yogurt):

- Sprinkle granules on one tablespoonful of soft food and consume immediately.
- Do not crush or chew the granules.

Giving ASPRUZYO Sprinkle with water through a 12 French or larger nasogastric (NG) tube:

- Add the granules from the sachet to a plastic catheter tip syringe and add 50 mL of water.
- Gently shake the syringe for about 15 seconds.
- Connect the catheter tip syringe to the NG tube and give the mixture right away.
- Make sure that no granules are left in the syringe. Rinse the syringe with about 15 mL of additional water if needed and give through NG tube.

Giving ASPRUZYO Sprinkle with water through a 12 French or larger gastric (G) tube:

- Add the granules from the sachet to a plastic catheter tip syringe and add 30 mL of water.
- Gently shake the syringe for about 15 seconds.
- Connect the catheter tip syringe to the G-tube and give the mixture right away.

- Rinse the syringe with 20 mL of additional water and give through G-tube.
- Make sure that no granules are left in the syringe. Rinse the syringe with about 15 mL of additional water if needed and give through G-tube.
- If you miss a dose of ASPRUZYO Sprinkle, take the next dose of ASPRUZYO Sprinkle at your regular time. Do not make up for the missed dose. Do not take 2 doses at the same time.
- If you take too much ASPRUZYO Sprinkle, call your healthcare provider, or go to the nearest emergency room right away.

What should I avoid while taking ASPRUZYO Sprinkle?

- You should limit grapefruit, grapefruit juice, and products that contain grapefruit during treatment with ASPRUZYO Sprinkle. Grapefruit products can increase the amount of ASPRUZYO Sprinkle in your body.
- ASPRUZYO Sprinkle can cause dizziness, lightheadedness, and fainting. If you have these symptoms, do not drive a car, use machinery, or do anything that needs you to be alert.
- You should not drink alcohol during treatment with ASPRUZYO Sprinkle.

What are the possible side effects of ASPRUZYO Sprinkle?

ASPRUZYO Sprinkle may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QT prolongation.** Your healthcare provider may check the electrical activity of your heart with an electrocardiogram (ECG). Tell your healthcare provider right away if you feel faint, lightheaded, or feel your heart beating irregularly or fast during treatment with ASPRUZYO Sprinkle. These may be symptoms related to QT prolongation.
- **Kidney failure in people who already have severe kidney problems.** Your healthcare provider may do blood tests to check your kidneys during treatment with ASPRUZYO Sprinkle.

The most common side effects of ASPRUZYO Sprinkle include:

- dizziness
- headache

- constipation
- nausea

These are not all of the possible side effects of ASPRUZYO Sprinkle.

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

How should I store ASPRUZYO Sprinkle?

- Store ASPRUZYO Sprinkle at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep ASPRUZYO Sprinkle and all medicines out of the reach of children.**

General information about the safe and effective use of ASPRUZYO Sprinkle.

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

What are the ingredients in ASPRUZYO Sprinkle?

Active ingredient: ranolazine

Inactive ingredients: amino methacrylate copolymer, dibutyl sebacate, ethyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, and talc.

Manufactured by:

Sun Pharmaceutical Industries Ltd.,
Mohali, INDIA

Distributed by:

Sun Pharmaceutical Industries, Inc.,
Cranbury, NJ 08512

For more information, call 1-800-818-4555.

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

Issued: February/2022