

Patient Information
RHAPSIDO® (RAP-si-doe)
(remibrutinib)
tablets, for oral use

What is RHAPSIDO?

RHAPSIDO is a prescription medicine used to treat adults with chronic spontaneous urticaria (CSU) who continue to have symptoms that are not controlled with antihistamine treatment.

RHAPSIDO should not be used to treat any other forms of hives (urticaria).

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

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

- have had a recent surgery or plan to have surgery. Your healthcare provider may tell you to stop taking RHAPSIDO for at least 3 to 7 days before and after any planned medical or surgical procedures.
- have bleeding problems or are taking a blood thinner medicine.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if RHAPSIDO will harm your unborn baby.
Pregnancy Exposure Registry: If you become pregnant during treatment with RHAPSIDO, talk to your healthcare provider about registering in the pregnancy exposure registry for RHAPSIDO. You or your healthcare provider can enroll in this registry by calling 1-888-669-6682. The purpose of this registry is to collect information about the safety of RHAPSIDO during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if RHAPSIDO passes into your breast milk. You and your healthcare provider should decide the best way to feed your baby while taking RHAPSIDO.
- have recently received or are scheduled to receive an immunization (vaccine). Talk to your healthcare provider about receiving any immunizations before taking RHAPSIDO. You should not receive live or live-attenuated vaccines during treatment with RHAPSIDO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking RHAPSIDO with certain other medicines may affect how RHAPSIDO works, or it may affect how other medicines work and can cause side effects.

How should I take RHAPSIDO?

- Take RHAPSIDO exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking RHAPSIDO unless your healthcare provider tells you to.
- Take 1 RHAPSIDO tablet 2 times a day.
- RHAPSIDO can be taken with or without food.
- Swallow RHAPSIDO tablet whole with water. **Do not** split, crush, or chew the tablets.
- If you miss a dose of RHAPSIDO, skip the missed dose, and take the next dose at your regular time. **Do not** take an extra dose of RHAPSIDO to make up for a missed dose.
- If you take too much RHAPSIDO, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are possible side effects of RHAPSIDO?

RHAPSIDO may cause serious side effects, including:

Risk of bleeding. Bleeding may happen while being treated with RHAPSIDO. Your healthcare provider will monitor you for signs and symptoms of bleeding and may stop your treatment if bleeding happens. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider right away if you get any signs or symptoms of bleeding, such as:

- bruising, or red or purple skin marks
- pink or brown urine
- headache, dizziness, confusion, or feeling weak
- red or black stools that look like tar

The most common side effects with RHAPSIDO may include nasal congestion, sore throat, and runny nose (nasopharyngitis), bleeding, headache, nausea, abdominal pain.

These are not all the possible side effects of RHAPSIDO.

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 RHAPSIDO?

- Store RHAPSIDO at room temperature between 68°F to 77°F (20°C to 25°C).
- Store RHAPSIDO in the original container to protect from moisture.

Keep RHAPSIDO and all medicines out of the reach of children.

General information about the safe and effective use of RHAPSIDO.

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

What are the ingredients in RHAPSIDO?

- Active Ingredient: remibrutinib
- Inactive Ingredients: copovidone, croscarmellose sodium, mannitol, microcrystalline cellulose, sodium lauryl sulfate, and sodium stearyl fumarate. The tablet coating is composed of polyethylene glycol 4000, polyvinyl alcohol, red iron oxide (E172), talc, titanium dioxide (E171), and yellow iron oxide (E172).

Distributed by:

Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936
For more information, go to www.RHAPSIDO.com or call 1-888-669-6682.

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

Issued: 9/2025

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