

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **RHAPSIDO**®

remibrutinib tablets

This Patient Medication Information is written for the person who will be taking **RHAPSIDO**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **RHAPSIDO**, talk to a healthcare professional.

What **RHAPSIDO** is used for:

RHAPSIDO is a prescription medicine used to treat a skin condition called chronic spontaneous urticaria. It is used in adults who continue to have symptoms despite treatment with antihistamines.

Chronic spontaneous urticaria is an unpredictable skin disease that is believed to be autoimmune in nature. Chronic spontaneous urticaria symptoms last at least 6 weeks and include the spontaneous and recurrent appearance of itchy wheals (hives), angioedema (swelling under the skin), or both.

How **RHAPSIDO** works:

RHAPSIDO works by blocking an enzyme in the body called Bruton's tyrosine kinase (BTK). When BTK is blocked, the release of histamine and other substances that cause inflammation is reduced. This helps to reduce the symptoms of chronic spontaneous urticaria.

The ingredients in **RHAPSIDO** are:

Medicinal ingredient(s): remibrutinib

Non-medicinal ingredients:

Tablet core: copovidone, croscarmellose sodium, mannitol, microcrystalline cellulose, sodium lauryl sulfate, sodium stearyl fumarate.

Tablet coating: polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

RHAPSIDO comes in the following dosage form(s):

Tablets; 25 mg.

The tablets are light yellow and round, curved, unscored with "LV" debossed on one side and the "Novartis" logo on the other side. The tablet diameter is 7 mm.

Do not use **RHAPSIDO** if:

- You are allergic to remibrutinib, or to any of the ingredients in RHAPSIDO.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RHAPSIDO. Talk about any health conditions or problems you may have, including if you:

- Have had a recent surgery or plan to have surgery. Your healthcare professional may tell you to stop taking RHAPSIDO for 3 to 7 days before and after any planned medical or surgical procedures.
- Have bleeding problems or are taking a blood thinner medication.
- Have liver problems.
- Have recently received or are scheduled to receive an immunization (vaccine).
- Are pregnant, think you may be pregnant or are planning to become pregnant.
- Are breastfeeding, or plan to breastfeed.

Other warnings you should know about:

Pregnancy: RHAPSIDO may harm your unborn baby. If you become pregnant during treatment with RHAPSIDO, talk to a healthcare professional **right away**. If you are a woman who could become pregnant, you must use effective contraception during your treatment and for at least 1 week after stopping RHAPSIDO treatment.

Risk of bleeding: Bleeding may occur during your treatment with RHAPSIDO. Your healthcare professional will monitor you for signs and symptoms of bleeding and may stop your treatment if bleeding happens. Tell your healthcare professional 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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RHAPSIDO:

- Medicines used to treat HIV infection, such as ritonavir.
- Medicines used to treat certain types of seizures (epilepsy), such as carbamazepine.
- Medicines used to treat heart problems such as digoxin.
- Medicines used to treat high cholesterol such as rosuvastatin.
- Medicines used to relieve pain, reduce fever or prevent blood clots such as aspirin (acetylsalicylic acid).
- Medicines used to treat blood clots such as clopidogrel.
- Medicines used to thin the blood such as warfarin.

How to take RHAPSIDO:

- Always take RHAPSIDO exactly as your healthcare professional has told you to. Check with your healthcare professional if you are not sure.

- Take RHAPSIDO tablets by mouth. Swallow the tablet whole with water. Do not split, crush, chew or break the tablet before swallowing.
- RHAPSIDO can be taken with or without food.
- Taking RHAPSIDO at the same time each day will help you to remember when to take your medicine.

Usual dose:

The usual recommended dose is 25 mg (one tablet) twice daily.

Overdose:

If you think you, or a person you are caring for, have taken too much RHAPSIDO, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose or doses, skip the missed dose and take your next dose at the regularly scheduled time. Do not take a double dose to make up for a forgotten dose.

Possible side effects from using RHAPSIDO:

These are not all the possible side effects you may have when taking RHAPSIDO. If you experience any side effects not listed here, tell your healthcare professional.

- Cold-like symptoms (upper respiratory tract infection)
- Bleeding (including purple or red spots on or under the skin, bruising, bleeding gums, nosebleed, bright red spot (broken blood vessel) in the white of the eye)
- Headache
- Nausea
- Stomach pain

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Do not store above 30°C.
- Keep out of reach and sight of children.
- Do not take this medicine after the expiration date listed on the carton.
- Ask your pharmacist how to dispose of medicines you no longer use.

If you want more information about RHAPSIDO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca); or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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