



Patient portrayal.

Introducing RHAPSIDO<sup>®</sup> (remibrutinib)

# A first-of-its-kind\* pill for chronic hives with no known external triggers

\*Treatment that inhibits histamine release by acting inside the mast cells.



Pill not actual size.

When antihistamines alone fall short,  
an oral option is finally here.

## Approved 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.

## Important Safety Information


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


- Have had a recent surgery or plan to have surgery. Your health care provider may tell you to stop taking RHAPSIDO for at least 3 to 7 days before and after any planned medical or surgical procedures


Please see Important Safety Information throughout and the [Summary of Important Information](#).





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## Important Safety Information (cont)

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

- 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. If you become pregnant during treatment with RHAPSIDO, talk to your health care provider about registering in the pregnancy exposure registry for RHAPSIDO

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# Chronic hives with no known external triggers: what you need to know

Chronic spontaneous urticaria (CSU), or chronic hives with no known external triggers, causes itchy, raised bumps (hives), swelling (angioedema), or both that last more than 6 weeks. Unlike other hives, these symptoms are not caused by something you ate, wore, or touched.



## Itchy hives

Hives are red or skin-colored, raised, and very itchy, often appearing and disappearing daily or almost daily without warning. Individual hives typically last 30 minutes to 24 hours, but the symptoms can repeat for years.



## Swelling

About 40% to 50% of people with chronic hives with no known external triggers also experience swelling (angioedema) in deeper layers of skin in areas like the lips, eyelids, hands, and feet. This swelling can last up to 72 hours and may occur with or without hives.



## A chronic condition

Chronic hives with no known external triggers can last 1 to 5 years, sometimes even longer. It's important to work with your doctor on a treatment plan that can help manage your symptoms long term.

## The impact



**1 in 2** people have symptoms while on antihistamines

**~50%** of people in a real-world study switched doctors up to 3 times in their treatment journey\*

\*Based on a real-world survey of 152 people diagnosed with chronic hives with no known external triggers (31% also had chronic inducible urticaria); 115 were treated with H1 antihistamines.

## Important Safety Information (cont)

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

- Are breastfeeding or plan to breastfeed. It is not known if RHAPSIDO passes into your breast milk

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# Fast relief from hives and itch in a pill— with results measured at week 12

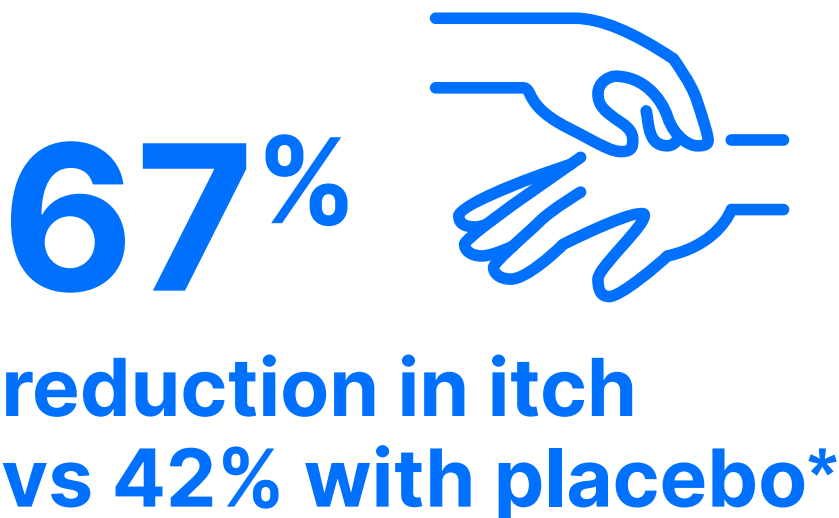
In one clinical study

## Results at **week 12**

Hives severity (HSS7) reduced 10.47 points with RHAPSIDO vs 6.00 with placebo on average from the start of the study.



Itch severity (ISS7) reduced 8.95 points with RHAPSIDO vs 5.72 with placebo on average from the start of the study.



\*These results were calculated from observed data. No statistical analyses were done and conclusions should not be drawn.

## Results at **week 2**

**~5x**

as many people had well-controlled hives and itch (UAS7 ≤6) at week 2 with RHAPSIDO (30% vs 5.9% with placebo)

## You deserve to find relief from ongoing hives and itch. RHAPSIDO could make that happen.

No matter how long you’ve had symptoms, how severe they are, or how many other treatments you’ve tried, RHAPSIDO may still be able to help you.

RHAPSIDO was studied in 2 identical clinical trials in adults (≥18 years of age) with chronic hives with no known external triggers who continued to have symptoms while taking antihistamines. All participants stayed on antihistamines while also taking either RHAPSIDO or placebo (in the trial presented: RHAPSIDO, n=297; placebo, n=153). Results were calculated based on least squares (LS) mean change from baseline and were similar between both trials.

### How hives and itch were measured:

- Participants rated hives and itch twice a day on 0 to 3 scales: the Hives Severity Score (HSS7) and the Itch Severity Score (ISS7). The worse the symptom, the higher the score
- The average daily ratings were added up each week and compared to their starting scores
- Scores for hives (HSS7) and itch (ISS7) can be combined into the Urticaria Activity Score (UAS7), which measures overall symptom severity. The total can range from 0 to 42, where 6 or less is well-controlled symptoms and 28 and over is severe symptoms

## Important Safety Information (cont)

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

- Have recently received or are scheduled to receive an immunization (vaccine). Talk to your health care provider about receiving any immunizations before taking RHAPSIDO. You should not receive live or live-attenuated vaccines during treatment with RHAPSIDO

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# RHAPSIDO<sup>®</sup> (remibrutinib) safety in clinical studies

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

## Nasopharyngitis

11% of those who took RHAPSIDO and 9% who took placebo

## Bleeding

9% of those who took RHAPSIDO and 2% who took placebo

Of the 9%, the most common types of bleeding were tiny red spots on the skin (4%) and bruising (2%)

## Headache

7% of those who took RHAPSIDO and 6% who took placebo

## Nausea

3% of those who took RHAPSIDO and 2% who took placebo

## Abdominal pain

3% of those who took RHAPSIDO and 2% who took placebo

These are not all of the possible side effects of RHAPSIDO.  
View the full [Prescribing Information](#) to learn more.

## Important Safety Information (cont)

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

### 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 health care 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 health care provider right away if you get any signs or symptoms of bleeding, such as:

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# Make RHAPSIDO part of your daily routine



Patient portrayal.  
Pill not actual size.

## No injections or additional office visits

### Starting RHAPSIDO

- Treatment with RHAPSIDO is a twice-daily pill you can take anywhere, with or without food
- The recommended dose of RHAPSIDO is 25 mg taken orally twice daily
- RHAPSIDO tablets should be swallowed whole with water, and should not be split, crushed, or chewed
- If a dose of RHAPSIDO is missed, it should be skipped, and the next dose should be taken at its regularly scheduled time. You should not take extra doses to make up for a missed dose or doses

### Staying on RHAPSIDO

- Chronic hives with no known external triggers can last for a while. Your doctor will determine how long you should take RHAPSIDO
- For RHAPSIDO to work the way it's meant to, it's important to continue taking it exactly as your doctor prescribed

## Important Safety Information (cont)

What are possible side effects of RHAPSIDO?

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

- o Bruising or red or purple skin marks
- o Pink or brown urine
- o Headache, dizziness, confusion, or feeling weak
- o Red or black stools that look like tar

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# Get the support you need

## Personalized support that can help you start, stay, and save on treatment

Once you’ve been prescribed RHAPSIDO® (remibrutinib), you or your loved one can sign up for Novartis Patient Support™.\* It’s a comprehensive program with a dedicated team in your corner. Sign up at [support.RHAPSIDO.com](https://support.RHAPSIDO.com).

### A helping hand when you need it:



#### Financial support

Learning about savings and other possible ways to afford your treatment, including Co-Pay Plus.†



#### Ongoing support

Get helpful resources and answers to your questions throughout your treatment.



#### Insurance support

Navigating the insurance process and understanding your insurance coverage information.

\*Novartis Patient Support does not provide clinical advice and is not a substitute for consulting with your doctor.

†**Limitations apply.** Valid only for those with private insurance. The Program includes the Co-Pay Plus offer, Plus Card (if applicable), and Rebate, with a combined annual limit. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient’s insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient’s insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited toward patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

### Important Safety Information (cont)

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

These are not all the possible side effects of RHAPSIDO.

Call your health care provider for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](https://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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# Summary of Important Information

## Important Facts about RHAPSIDO

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  - o Bruising or red or purple skin marks
  - o Pink or brown urine
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**This information is not comprehensive.**

To learn more, talk to your health care provider or visit [www.rhapsido.com](http://www.rhapsido.com) to obtain the FDA-approved product labeling.







Learn more at [rhapsido.com](https://rhapsido.com)

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