

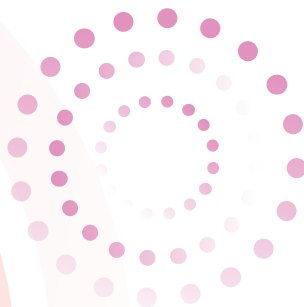
Chronic Spontaneous Urticaria (CSU)
**My Treatment with Rhapsido®
(Remibrutinib)**

Intended only for patients who have already been prescribed Rhapsido®.



MY TREATMENT WITH RHAPSIDO (REMIBRUTINIB)

A diagnosis of chronic spontaneous urticaria (CSU) can feel overwhelming—and it's perfectly normal to have questions. This guide is designed to help you understand what CSU is. It also offers practical tips for everyday life and helps you get started with your treatment.



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WHAT IS CHRONIC SPONTANEOUS URTICARIA?

Urticaria is often referred to as hives. It can be acute (short-term) or chronic (if the symptoms last longer than six weeks). Chronic urticaria can also be classified as *inducible* (caused by a specific trigger) or *spontaneous* urticaria (unpredictable onset without a recognizable external trigger). Chronic spontaneous urticaria (CSU) is an immune-mediated skin condition that affects about 1 in 100 people.

Typical symptoms of CSU include red, itchy hives and swelling of the skin. It can significantly affect one's mood and daily life—for example, sleep, work, and relationships.

"Although CSU is not contagious and poses no danger to others, the condition has had a major impact on my life. What was particularly difficult for me was how other people reacted to it. At first, I felt ashamed, too, and withdrew from others at times, which led to fewer social interactions. The severe itching was already very physically taxing, but the psychological and emotional strain was even worse. I often felt very lonely and alone in that situation.

Because of my sleep problems, I had a hard time concentrating. At the same time, work was also an important distraction for me, one that helped me take my mind off things—at least for a while."

Melitta

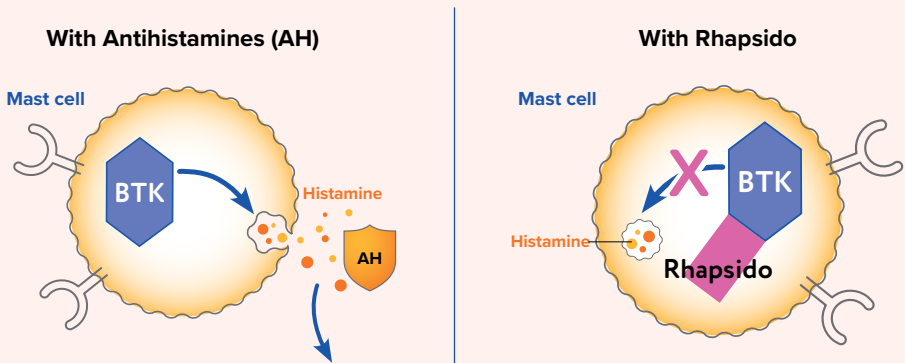
Even though CSU often causes symptoms that resemble those of allergies, it is not an allergy. It is triggered by the immune system—the body's natural defence against diseases and infections. The immune system protects us by fighting off bacteria or viruses that enter the body.

In CSU, the immune system is overactive and mistakenly identifies harmless molecules as a threat. This triggers an immune response and causes the release of a messenger substance called histamine. **Histamine** then affects the skin and can cause redness, swelling, and itching.



WHY WAS RHAPSIDO PRESCRIBED TO ME, AND HOW DOES IT WORK?

Your doctor has prescribed you this medication to treat your CSU and relieve your symptoms. In CSU, certain cells of the immune system—known as mast cells—are activated in an uncontrolled manner. **Mast cells** release **histamine**, which can cause skin symptoms such as itching, hives, redness, and swelling. An enzyme in these mast cells—**Bruton's tyrosine kinase (BTK)**—plays an important role in this process. In this case, **antihistamines** are often the first-line treatment and act as a protective shield: They block the effects of histamine after it has already been released. Rhapsido attacks first: It inhibits the BTK enzyme in the cells, preventing histamine from being released in the first place. This can help reduce the symptoms caused by histamine.



Signs and Symptoms of CSU



Hives



Deep tissue swelling
(angioedema)



Itching

HOW DO I TAKE THIS MEDICATION?

The treatment consists of a tablet taken **twice a day**. Take **one 25 mg** tablet in the morning and one in the evening. Swallow each tablet whole with water. Do not split, crush, or chew the tablet before swallowing it. It's best to take your medication at the same time every day. When taken regularly, it can alleviate the symptoms of your chronic spontaneous urticaria and reduce the likelihood of new flare-ups. Use the motivational cards and stickers in your starter kit to help you remember to take your daily dose.

It is important that you continue to take the medication even if you are already feeling better. Don't wait until your symptoms return.

Tip for making it easier to incorporate the medication into your daily routine:

Take your tablet, for example, whenever you brush your teeth in the morning and at night.





QUESTIONS AND ANSWERS ABOUT THE DURATION OF MY TREATMENT

How quickly can the treatment take effect?

The response to treatment varies from person to person and depends, for example, on the severity of the disease and the individual's immune response. More than 8 out of 10 study participants noticed an improvement within just a few weeks, and some became symptom-free.

Does a CSU flare-up at the start of treatment mean that the treatment isn't working?

Don't worry if you continue to experience CSU flare-ups—especially at the beginning of treatment. It may take some time for the treatment to take full effect. If your symptoms persist, talk to your doctor about whether your treatment should be adjusted.

Why should this treatment be taken long-term?

Once you have achieved remission—that is, a significant improvement in your symptoms—while undergoing treatment, this indicates that the disease is well controlled. It does not mean that the disease has been cured. The disease can become active again even after a prolonged symptom-free period. Therefore, it is important to continue the treatment as prescribed by your doctor on a long-term basis.

Your treating physician will check at regular intervals to determine whether treatment is necessary. If you stop treatment on your own, your CSU symptoms may return. Therefore, do not stop taking this medication without consulting your doctor.

PREGNANCY AND BREASTFEEDING

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are a woman of childbearing age, you must use an effective method of contraception (birth control) during treatment and for at least one week after completing treatment with Rhapsido. Ask your doctor about effective methods of contraception.

You must not breastfeed during treatment with Rhapsido and for one week after treatment ends, as it is not known whether Rhapsido passes into breast milk.





WHAT ARE THE POSSIBLE SIDE EFFECTS OF THE TREATMENT?

Like all medicines, Rhapsido can also cause side effects, although not everybody gets them. Most side effects—if they occur—are generally mild to moderate.

Very common (may affect more than 1 in 10 people):

- Nose and throat infections (upper respiratory tract infections)

Common (may affect up to 1 in 10 patients treated)

- Fever (pyrexia)
- Herpes virus infections
- Headache
- Bruises
- Small red spots under the skin (petechiae)
- Bruises under the skin (contusions)
- A bleeding area under the skin with a blue or purple bruise (ecchymosis)
- Pink or brown urine (haematuria)
- Malaise (nausea)
- Lower abdominal pain
- Backache

Uncommon (may affect up to 1 in 100 patients treated)

- Nosebleeds (epistaxis)
- Purple or reddish-brown spots on the skin (purpura)
- A flat, light red spot in the white of the eye (conjunctival haemorrhage)
- Bleeding gums (gingival bleeding)

For more information on possible side effects, please refer to the package insert.

If you notice any side effects, talk to your doctor. This includes any side effects not listed in this brochure.

It may be helpful to keep track of how you feel during treatment. The patient journal included in the starter kit can help you keep track of any changes or side effects.



HOW CAN I BEST MANAGE MY CSU AND MY DAILY LIFE DURING TREATMENT?

Write it down

A journal, such as the patient journal included in your starter kit, can help you track how your situation has changed since you began treatment. If you keep track of small changes—such as fewer flare-ups, less itching, or better sleep—it can help you recognize your progress and stay motivated. You can also discuss these observations with your doctor.

Missed a dose?

If you miss a dose, skip it and take the next dose at the usual time. Do not take an extra dose to make up for the one you missed.

Did you take more than intended?

If you have taken more than you should, talk to a doctor right away. When you go to a doctor's office or the hospital, be sure to bring the pill bottle and the package insert with you.



Travel with Rhapsido

No special storage conditions are required for your medication. If you are bringing your medication on a plane, it is a good idea to keep it in its original packaging along with your doctor's prescription.

Get support

CSU can sometimes feel overwhelming. A network of family and friends can help ensure that you don't have to deal with this alone.

If you talk openly about your condition, the people around you will be better able to understand what you're going through—and support you accordingly. You might also want to ask someone to accompany you to your appointment. A support person can provide you with emotional support, ask questions, and take notes on important information so that nothing is forgotten.

Working with CSU

CSU symptoms can interfere with sleep, well-being, and concentration, and can thus affect energy levels, mood, and work performance.

To ensure that your work situation better accommodates your medical condition, it may be helpful to share specific experiences with a manager you trust or a contact person in Human Resources. It is possible that additional support or resources may be available there.





HOW CAN I PREPARE FOR DOCTOR'S APPOINTMENTS?

Doctor's appointments are a good opportunity to discuss the progress of your treatment. If you share how you're feeling and what changes you've noticed, your doctor will be better able to assess whether your CSU treatment plan is still appropriate. Talking about the illness can sometimes feel difficult—but being well-prepared can make these conversations easier.

Things you can discuss with your doctor:

- **How your symptoms have progressed:**
Have the hives, itching, or swelling changed or improved?
- **How your quality of life has changed:**
How do you sleep? Have your mood, energy level, or ability to concentrate improved at work or during social activities?
- **How you take your medication:**
How consistently were you able to take it?
- **Any side effects you may have noticed:**
Describe these as specifically as possible.
- **Whatever questions you may have:**
Regarding your treatment to date

Here's how to make the most of a time-limited appointment:

- **Bring someone along for support:** for example, a family member or friend, if that would be helpful to you.
- **Take your notes with you:** Make a list of all medications and dietary supplements you are taking, including their dosages. If you are also taking antihistamines, note the frequency and dosage.
- **Write down your questions:** Write down important questions and topics in advance.
- **Keep a record of the course of the illness:** Keep track of any changes in your symptoms as they occur in your daily life, for example, in your patient journal.
- **Describe the effects of the disease:** Explain how the CSU affects sleep, mood, work, and social life.
- **Share changes:** Please tell us what has changed or improved since your last appointment.
- **Confirm your treatment plan:** Make sure you understand the dosage and schedule.



Remember:
Being open and specific will
help your doctor understand
your situation and tailor your
treatment to your needs.



USEFUL TIPS AND TOOLS

1) Set up a calendar entry (e.g., on your smartphone)

Open your Calendar app. Create a "Take medication" appointment (morning/evening). Set the appointment to "repeat daily." Set a reminder (e.g., 10 minutes beforehand).

Tip: Choose set times that fit into your routine (e.g., after brushing your teeth).

2) Use a mobile phone reminder or alarm clock

- Set two daily alarms (morning/evening).
- Give the alarm a unique name (e.g., "Medication").
- If possible, use a feature such as "Remind me until completed."

3) Visual reminders around the house

Place a discreet reminder in places you're sure to see in the morning or evening, such as:

- **in front of the bathroom mirror**
- **at the coffee machine**
- **on the nightstand**
- **on the refrigerator**

Good options include, for example, the stickers you'll find in the starter kit or small sticky notes that you see regularly.



Stay informed

You can also find more information about urticaria at hautwende.de/urtikaria or through the "Hautwende" communities on Facebook and Instagram.





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Before using Rhapsido, please read the full package insert at www.novartis.com.

Talk to your doctor, if you:

- Have questions about the medication or your treatment plan.
- Notice side effects—including those not listed in the package insert.

Useful Addresses and Contacts

The following patient organizations and associations can offer support during your treatment.

Deutscher Allergie- und Asthmabund e.V.
[German Allergy and Asthma Association] (DAAB)
An der Eickesmühle 15–19, 41238 Mönchengladbach

Phone 02166 6478888
(DAAB Hotline for those seeking advice:
Mon.–Thu.: 9:00 a.m.–12:00 p.m.)

E-Mail info@daab.de
Website <http://www.daab.de>

Urtikaria-Helden gUG
Saubornstraße 3, 56073 Koblenz

E-Mail infos@urtikaria-helden.de
Website <http://www.urtikaria-helden.de>

Die Urtikarianer [The Urticarian]

E-Mail info@die-urtikarianer.de
Website <http://www.die-urtikarianer.de>

DO YOU HAVE ANY MEDICAL QUESTIONS about Novartis products or your condition that is being treated with Novartis products, e.g.:

- Taking the medication
- Possible side effects or complaints
- Effectiveness
- Combinations, interactions with other medications?

Please feel free to contact us, the Novartis Pharma Medical Information Service, at:

(Mon. to Fri. from 8:00 a.m. to 6:00 p.m)

Phone 0911 273 12 100
Fax 0911 273 12 160
E-Mail infoservice.novartis@novartis.com
Website www.infoservice.novartis.de
Live-Chat www.chat.novartis.de