

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Rhapsido?

Rhapsido contains the active ingredient remibrutinib. Rhapsido is a prescription medicine used to treat adults with chronic spontaneous urticaria (CSU) who continue to have CSU symptoms despite treatment with antihistamines.

For more information, see Section [1. Why am I using Rhapsido?](#) in the full CMI.

2. What should I know before I use Rhapsido?

Do not use if you have ever had an allergic reaction to Rhapsido or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Talk to your doctor if you have bleeding problems or are taking a blood thinner medicine.

For more information, see Section [2. What should I know before I use Rhapsido?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rhapsido and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Rhapsido?

- Rhapsido is taken as one tablet twice a day by mouth. Swallow the tablet whole with water.
- Do not split, crush, chew or break the tablet before swallowing as it may change how much medicine gets into your body.
- Rhapsido can be taken with or without food.

More instructions can be found in Section [4. How do I use Rhapsido?](#) in the full CMI.

5. What should I know while using Rhapsido?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Rhapsido. • Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, herbal medicines and supplements. • If you are a woman who could become pregnant, you should use an effective birth control during treatment and for 1 week after stopping Rhapsido treatment. • Check with your doctor if you are pregnant or intend to become pregnant.
Things you should not do	• You should not receive live or live-attenuated vaccinations during treatment with Rhapsido. • Do not breast-feed during treatment with Rhapsido and for one week after stopping treatment, as it is not known if Rhapsido transfers into human milk. • Do not stop taking your medicine unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Rhapsido affects you.
Looking after your medicine	• Store your tablets in a cool dry place below 30 degrees in the original container.

For more information, see Section [5. What should I know while using Rhapsido?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of Rhapsido include cold-like symptoms, tiny red spots on the skin, bruising under the skin, a bleeding spot under the skin with blue or purplish patch.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Rhapsido®

Active ingredient(s): remibrutinib

Consumer Medicine Information (CMI)

This leaflet provides important information about using Rhapsido. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Rhapsido.**

Where to find information in this leaflet:

1. [Why am I using Rhapsido?](#)
2. [What should I know before I use Rhapsido?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Rhapsido?](#)
5. [What should I know while using Rhapsido?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Rhapsido?

Rhapsido contains the active ingredient remibrutinib. Remibrutinib belongs to a group of medicines called Bruton's tyrosine kinase (BTK) inhibitors.

Rhapsido is used to treat adults with chronic spontaneous urticaria (CSU) who continue to have CSU symptoms despite treatment with antihistamines.

BTK is essential for the activity of specific receptors on cells in your body which play a key role in causing CSU. Rhapsido works by blocking BTK, which neutralises the cell activity involved in the inflammation pathways (reason for the cause of itch, hives or swelling), and reduces the frequency and severity of CSU symptoms.

2. What should I know before I use Rhapsido?

Warnings

Do not use Rhapsido if:

- you are allergic to remibrutinib or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Talk to your doctor if you have bleeding problems or are taking a blood thinner medicine.

Do not give Rhapsido to children or adolescents below 18 years of age. This is because it has not been studied in this age group.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

If you are a woman who could become pregnant, you should use effective birth control during treatment and for 1 week after stopping Rhapsido treatment.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. **Do not breast-feed during treatment with Rhapsido and for one week after stopping treatment, as it is not known if Rhapsido transfers into human milk.**

Tell your doctor if you have recently had surgery or plan to have surgery. Your doctor may ask you to stop taking Rhapsido for 3 to 7 days before and 3 to 7 days after any planned medical or surgical procedures.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Rhapsido and affect how it works.

Tell your doctor if you are taking any of the following medicines:

- 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, decrease 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.
- medicines used as contraceptives, such as ethinylestradiol and levonorgestrel.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rhapsido.

4. How do I use Rhapsido?

How much to take

- The recommended dose is 25 mg twice a day. Follow the instructions provided and use Rhapsido until your doctor tells you to stop.

When to take Rhapsido

- Rhapsido should be taken at the same time each day and this will help you to remember when to take your medicine.

How to take Rhapsido

- Swallow the tablet whole with water.
- Do not split, crush, chew or break the tablet before swallowing as it may change how much medicine gets into your body.
- Rhapsido can be taken with or without food.

If you forget to use Rhapsido

- Rhapsido should be used regularly at the same time each day. If you miss your dose at the usual time, then you should take the next dose at your usual time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Rhapsido

If you think that you have used too much Rhapsido, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Rhapsido?

Things you should do

Tell your doctor or pharmacist if you have recently had a vaccination. You should not receive live or live-attenuated vaccinations during treatment with Rhapsido. If you are due to have a vaccination with a non-live vaccine, your doctor may interrupt treatment with Rhapsido for 1 week before a planned vaccination until 2 weeks after vaccination.

Tell your doctor if you have recently had surgery or plan to have surgery. Your doctor may ask you to stop taking Rhapsido for 3 to 7 days before and 3 to 7 days after any planned medical or surgical procedures.

Remind any doctor, dentist or pharmacist you visit that you are using Rhapsido.

Things you should not do

- Do not stop using this medicine suddenly. Stopping your treatment with Rhapsido may cause your CSU symptoms to return.
- Do not split, crush, chew or break the tablet before swallowing as it may change how much medicine gets into your body.
- Do not breast-feed during treatment with Rhapsido and for one week after stopping treatment, as it is not known if Rhapsido transfers into human milk.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Rhapsido affects you.

Rhapsido may cause dizziness in some people.

Looking after your medicine

- Store your tablets in a cool dry place below 30°C in the original container
- Do not store it in the bathroom or near a sink, in the car, or on windowsills.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Do not take this medicine after the expiration date, which is stated on the carton.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Cold-like symptoms (upper respiratory tract infections) • Tiny red spots on the skin • A bleeding spot under the skin with blue or purplish patch • Bruising under the skin • Nosebleed • Red patch in white of eye	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Bleeding or bruising	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Rhapsido contains

Active ingredient (main ingredient)	remibrutinib
Other ingredients (inactive ingredients)	mannitol, microcrystalline cellulose, copovidone, croscarmellose sodium, sodium stearyl fumarate, sodium lauryl sulfate, polyvinyl alcohol, titanium dioxide, iron oxide yellow, iron oxide red, purified talc, macrogol 4000
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What Rhapsido looks like

Rhapsido is supplied as film-coated tablets. Each tablet is light yellow, round, curved, unscored film-coated tablet with diameter 7 mm, debossed with "LV" on one side and "Novartis" logo on the other side. Blister packs of 30, 60, or 180 tablets (not all pack sizes may be available); AUST R 485465.

Who distributes Rhapsido

Rhapsido is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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