

Package leaflet: Information for the patient

Rhapsido 25 mg film-coated tablets remibrutinib

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rhapsido is and what it is used for
2. What you need to know before you take Rhapsido
3. How to take Rhapsido
4. Possible side effects
5. How to store Rhapsido
6. Contents of the pack and other information

1. What Rhapsido is and what it is used for

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

Rhapsido is used to treat adults with chronic (long-term) spontaneous urticaria (CSU) when treatment with antihistamines does not work well enough.

In people with CSU, symptoms can happen when the immune system (the body's natural defences) becomes overactive. Certain immune cells switch on a protein called Bruton's tyrosine kinase, which causes hives, itching and/or swelling. Remibrutinib works by blocking BTK which helps stop the immune cells from becoming overactive and reduces inflammation, making CSU symptoms less frequent and less severe.

2. What you need to know before you take Rhapsido

Do not take Rhapsido

- if you are allergic to remibrutinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Rhapsido:

- if you have or have ever had unusual bruising or bleeding, or are taking any medicines that could increase your risk of bleeding. See section "Other medicines and Rhapsido" below.
- if you have recently had any surgery or are planning to have surgery. Your doctor may ask you to stop taking Rhapsido for a short time before (3 to 7 days) and after (3 to 7 days) your surgery.
- if you have recently had a vaccination or are planning to have a vaccination. Certain types of vaccines (known as live or live-attenuated vaccines) are not recommended to be used during

treatment with Rhapsido. If you have had, or are planning to have another type of vaccine (known as a non-live vaccine), your doctor may ask you to stop taking Rhapsido for 1 week before and 2 weeks after the vaccination.

- if you are taking any other medicines as these could interact with Rhapsido. See section “Other medicines and Rhapsido” below.

Children and adolescents

Do not give this medicine to children or adolescents below 18 years of age. It has not been studied in this age group.

Other medicines and 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.

Rhapsido may make you bleed more easily. This means you should tell your doctor if you take any other medicines or supplements that increase your risk of bleeding (see “Warnings and precautions” above). This includes any of the following:

- medicines used to relieve pain, reduce fever or prevent blood clots, such as acetylsalicylic acid.
- medicines used to treat blood clots, such as clopidogrel.
- medicines used to thin the blood, such as warfarin.

Tell your doctor or pharmacist if you are taking any of the following medicines as they may increase the risk of side effects of Rhapsido, or Rhapsido may increase the risk of side effects of them:

- medicines used to treat HIV infection, such as ritonavir.
- medicines used to treat heart problems, such as digoxin.
- medicines used to treat high cholesterol, such as rosuvastatin.
- medicines used for sedation or sleep disturbances, such as midazolam.

Tell your doctor or pharmacist if you are taking any of the following medicines as they may decrease the effectiveness of Rhapsido:

- medicines used to treat certain types of seizures, such as carbamazepine.

Tell your doctor or pharmacist if you have recently had a vaccination or plan to have a vaccination (see “Warnings and precautions” above).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Treatment with Rhapsido is not recommended during pregnancy or in women who can become pregnant who are not using effective contraception (birth control). This is because studies in animals have shown that Rhapsido may cause harm to the unborn baby.

Do not breast-feed during treatment with Rhapsido and for one week after stopping treatment, as it is not known if Rhapsido passes into breast milk.

If you are a woman who could become pregnant, you must use an effective method of contraception (birth control) during treatment with Rhapsido and for at least one week after stopping treatment. Ask your doctor about effective methods of contraception.

Driving and using machines

Rhapsido has no or negligible influence on the ability to drive and use machines.

Rhapsido contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially “sodium-free”.

3. How to take Rhapsido

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 25 mg tablet twice a day, once in the morning and once in the evening.

- Swallow the tablet whole with water.
- Do not split, crush or chew the tablet before swallowing as this may change how much medicine gets into your body.
- To help you remember to take Rhapsido, take it at the same time every day.
- Rhapsido can be taken with or without food.

Rhapsido and surgery

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.

If you take more Rhapsido than you should

If you take more Rhapsido than you should, talk to a doctor straight away. If you are told to go to the hospital, take the tablet pack and this leaflet with you.

If you forget to take Rhapsido

If you miss a dose then you should take the next dose at your usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Rhapsido

Stopping your treatment with Rhapsido may cause your CSU symptoms to return. Do not stop taking Rhapsido unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All of the following side effects are 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 people)

- Herpes virus infection
- Headache
- Bruising
- Tiny red spots under the skin (petechiae)
- Bruising under the skin (contusion)
- A bleeding spot under the skin with blue or purplish patch (ecchymosis)
- Pink or brown urine/blood in the urine (haematuria)
- Feeling sick (nausea)
- Abdominal pain
- Back pain
- Fever (pyrexia)

Uncommon (may affect up to 1 in 100 people)

- Nosebleed (epistaxis)

- Purple or red-brown spots on the skin (purpura)
- A flat, bright red patch in the white of the eye (conjunctival bleeding)
- Bleeding gums (gingival bleeding)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rhapsido

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister foil after “EXP”. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rhapsido contains

- The active substance is remibrutinib. Each film-coated tablet contains 25 mg of remibrutinib.
- The other ingredients are mannitol, microcrystalline cellulose, copovidone, croscarmellose sodium, sodium stearyl fumarate, sodium lauryl sulfate. The tablet coating is composed of polyvinyl alcohol, macrogol 4000, talc, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

What Rhapsido looks like and contents of the pack

Rhapsido is supplied as 25 mg film-coated tablets. The tablets are light yellow, round and curved. They have “LV” on one side and the company logo on the other side. The tablet diameter is approximately 7 mm.

Rhapsido is supplied in blisters and is available in packs containing 30, 60 or 180 film-coated tablets. Not all pack sizes may be marketed.

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