

Package leaflet: Information for the patient

REZUROCK 200 mg film-coated tablets

Belumosudil

Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

▼ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Rezurock is and what it is used for

What Rezurock is

The active substance is called belumosudil.

Belumosudil belongs to a group of medicines called immunosuppressants. It works by blocking an enzyme called ROCK2 that is involved in how your immune system works.

What Rezurock is used for

Rezurock is used to treat adults and adolescents aged 12 years and older with chronic graft-versus-host disease who have received at least two previous treatments.

What chronic graft-versus-host disease is

Chronic graft-versus-host disease can happen after you have a bone marrow or stem cell (blood) transplant. The cells transplanted from the donor (the graft) attack your body (the host). This disease can cause damage to many organs like your skin, liver or digestive system.

2. What you need to know before you take Rezurock

Do not take Rezurock

- if you are **pregnant** since Rezurock can harm your unborn baby (see section “Pregnancy, breast-feeding and fertility”).
- if you are **allergic** to belumosudil or any of the other ingredients of this medicine (listed in section 6).

If you are uncertain whether the conditions above apply to you, talk to your doctor, pharmacist or nurse before taking Rezurock.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Rezurock, if you:

- **plan to become pregnant**, since Rezurock can harm your unborn baby (see section “Pregnancy, breast-feeding and fertility”).
- **are breast-feeding or plan to breast-feed**, since Rezurock may potentially cause serious side effects in a breast-fed child (see section “Pregnancy, breast-feeding and fertility”).
- have any **kidney** problems.
- have any **liver** problems.
- are taking other medicines (see section “Other medicines and Rezurock”).

You should have blood tests before and during treatment with Rezurock including tests to monitor how well your liver is working.



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Children

Rezurock is not recommended for use in children under 12 years old.

Other medicines and Rezurock

Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Rezurock may affect the way other medicines work, and other medicines may affect the way Rezurock works.

Especially tell your doctor if you are taking any of the medicines in the table below as your doctor may need to change the dose of these medicines or the dose of Rezurock:

Medicine	Purpose of the medicine	Potential effect
rifampicin	for tuberculosis	These medicines might decrease the concentration of belumosudil.
dexamethasone	for allergies or inflammation	
carbamazepine, phenytoin	for seizures	
efavirenz	for HIV	
benzodiazepines like midazolam	to cause drowsiness	
proton pump inhibitors like omeprazole or rabeprazole	to lower acid production in the stomach	
other gastric acid reducing agents like ranitidine		Belumosudil might increase the concentration of these medicines since it slows their breakdown in your body.
statins like atorvastatin	to lower cholesterol	
beta blockers like carvedilol	to lower blood pressure	
calcium channel blockers like diltiazem		
ciclosporin	to suppress the immune system	
antibiotics like amoxicillin or clarithromycin	for bacterial infections	
digoxin	to regulate the heart beat	
docetaxel	for chemotherapy	
antifungals like clotrimazole	for fungal infections	

If you are not sure if any of the above apply to you, talk to your doctor before taking Rezurock.

While you are taking Rezurock you should never start a new medicine without checking first with your doctor. This includes prescription medicines, non-prescription medicines (over-the-counter medicines) and herbal or alternative medicines.

Keep a list of all the medicines you take to show your doctor and pharmacist when you get a new medicine.

Rezurock with food

Rezurock should be taken with food. See section 3.

Pregnancy, breast-feeding and fertility

Tell your doctor **immediately** if you are pregnant, think you may be pregnant, or if you are breast-feeding. If you are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Do not take Rezurock during pregnancy because Rezurock can harm your unborn baby. Your doctor will check if you are pregnant before starting the treatment. If you become pregnant whilst taking Rezurock, speak to your doctor immediately.

If you are a woman who is able to become pregnant, your doctor will check if you are pregnant before starting treatment with Rezurock. This is because Rezurock can harm an unborn baby. You must use a reliable and highly effective method of contraception during your entire treatment with Rezurock and for at least one week after the last dose.

If you are a man with a female partner who is able to become pregnant, your partner should avoid becoming pregnant whilst you are taking Rezurock. You must use a highly effective method of contraception during your entire treatment with Rezurock and for at least one week after the last dose.

Talk to your doctor about how to take appropriate measures of contraception during your treatment with Rezurock.

Breast-feeding

You **should not breast-feed** during treatment with Rezurock and for at least one week after the last dose because Rezurock may be harmful to a breast-fed child.

Fertility

Based on animal studies, Rezurock may cause temporary infertility. Effects were reversible.



Driving and using machines

Rezurock may affect your ability to drive or use machines. You may feel tired or dizzy while taking Rezurock. Do not drive or operate machines if you have these side effects.

Rezurock contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free'.

3. How to take Rezurock

Rezurock is prescribed to you by a doctor with experience of treating chronic graft-versus-host-disease.

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

The recommended dose for adults and adolescents (12 years of age or over) is one tablet (containing 200 mg of belumosudil) taken once daily orally at about the same time each day.

Your doctor may increase your dose of Rezurock if you are also taking certain drugs that can affect how belumosudil works.

Swallow the tablet whole with a glass of water with a meal.

Do not cut, crush or chew Rezurock tablets.

Your doctor may tell you to stop taking Rezurock for a while or permanently stop treatment depending on how you tolerate the treatment.

If you take more Rezurock than you should

If you take too much Rezurock, tell your doctor or go to the nearest hospital right away. Take the medicine pack with you.

If you forget to take Rezurock

If you miss a dose of Rezurock, take it as soon as you remember on the same day if it is less than 12 hours since your dose was due. Take your next dose of Rezurock at your regular time on the next day. If it is more than 12 hours since your dose was due, do not take the dose and take your next dose of Rezurock at your regular time on the next day. Do not take extra doses of Rezurock to make up for a missed dose.

If you are sick after taking Rezurock

If you are sick (vomit) after taking Rezurock, do not take another dose of Rezurock. Take your next dose of Rezurock at your regular time on the next day.

Duration of treatment with Rezurock

You should continue treatment until your doctor tells you to stop.

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. Some side effects can be serious.

Tell your doctor straight away if you experience any of the following rare serious side effects which may affect less than 1 in 10,000 people:

- Cough, chest pain, difficulty breathing, fever and sweating/chills. These could be symptoms of pneumonia.
- Painful, hot, swollen or blistering skin.
- Bloody diarrhoea.

Other side effects

Other possible side effects include the following listed below. If these side effects become severe, tell your doctor.

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

- Extreme tiredness
- Feeling sick (nausea)

Common (may affect up to 1 in 10 people):

- Headache
- Increase in aspartate aminotransferase (a liver enzyme)
- Increase in alanine aminotransferase (a liver enzyme)
- Diarrhoea
- Muscle or joint pain
- Being sick (vomiting)
- Increase in gamma glutamyl transferase (a liver enzyme)
- Low white blood cell count (cells that fight infection)
- Swelling
- Muscle spasms
- Upper respiratory tract infections (such as common cold, sinus infection)



Common (may affect up to 1 in 10 people):

- Sudden shortness of breath or difficulty breathing (dyspnea)
- Cough
- High blood sugar (hyperglycaemia)
- Decrease in appetite
- Increase in alkaline phosphatase in the blood (a muscle enzyme)
- Decrease in weight
- Low red blood cell count (anaemia)
- Pain, tingling or numbness in the hands or feet (neuropathy peripheral)
- High blood pressure
- Low platelet count (cells that fight bleeding)
- Lower respiratory tract infections (such as pneumonia, bronchitis)
- Pain in the stomach
- Constipation
- Itching
- Dizziness
- Increase in creatinine phosphokinase in the blood (a muscle enzyme)
- Increase in creatinine in the blood (a muscle waste product)
- Fever

Your doctor may change your dose of Rezurock, temporarily stop, or permanently stop treatment with Rezurock if you have certain side effects.

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. You can find information on this at 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 Rezurock

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 bottle after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original container to protect from moisture.

Tightly close the bottle of Rezurock after you take your dose.

The Rezurock bottle contains a desiccant packet to help keep your tablets dry (protect from moisture). Keep the desiccant in the bottle.

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 Rezurock contains

The active substance is belumosudil mesilate. Each tablet contains 200 mg belumosudil.

The other ingredients are:

Tablet core: microcrystalline cellulose, hypromellose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate.

Tablet coating: polyvinyl alcohol (E1203), polyethylene glycol (E1521), talc (E553b), titanium dioxide (E171), yellow iron oxide (E172).

What Rezurock looks like and contents of the pack

Rezurock film-coated tablets are pale yellow oblong tablets debossed with "KDM" on one side and "200" on the other side.

Rezurock is available in a plastic bottle with a child-resistant closure in a pack-size of 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sanofi,
410 Thames Valley Park Drive,
Reading,
Berkshire, RG6 1PT,
United Kingdom

Manufacturer:

Sanofi Winthrop Industrie,
30-36 avenue Gustave Eiffel,
37100 Tours,
France

This leaflet was last revised in September 2022.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

