

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rREZUROCK™

Belumosudil tablets

Read this carefully before you start taking **REZUROCK** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REZUROCK**.

What is REZUROCK used for?

REZUROCK is used to treat patients, 12 years of age and older, with chronic graft-versus-host disease (GVHD) after two or more prior treatments that did not work.

How does REZUROCK work?

- REZUROCK blocks a specific protein in the body that is involved in inflammation and fibrosis. This may help to decrease symptoms of chronic GVHD like inflammation and scarring.

What are the ingredients in REZUROCK?

- Medicinal ingredient: belumosudil mesylate.
- Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide and yellow iron oxide.

REZUROCK comes in the following dosage forms:

Tablets: 200 mg belumosudil (as belumosudil mesylate).

Do not use REZUROCK if:

- you are allergic to belumosudil or to any ingredient in this medicine or container.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REZUROCK. Talk about any health conditions or problems you may have, including if you:

- have a gastrointestinal infection.
- have liver or kidney problems.

Other warnings you should know about:

Hypertension and hypotension (high and low blood pressure): REZUROCK can infrequently cause high or low blood pressure. Your healthcare professional will check your blood pressure before and during treatment.

Gastrointestinal problems: REZUROCK can cause diarrhea, severe nausea, vomiting and dehydration. Your healthcare professional will treat these problems as needed.

Blood and bleeding problems: REZUROCK may infrequently cause blood problems like lymphopenia and neutropenia (low white blood cells), **thrombocytopenia** (low blood platelets), and **anemia** (low red blood cells). Your healthcare professional will do blood tests monthly. REZUROCK can also cause bleeding problems.

Infections: REZUROCK can cause mainly bacterial or viral infections, which most often affect the organs involved in breathing (called respiratory system) such as lungs and the upper respiratory system. Your healthcare professional will treat these infections as needed.

Liver problems: REZUROCK can cause an increase in liver function tests. You will have regular blood tests done before starting your treatment and while you are taking REZUROCK. These blood tests will tell your healthcare professional how your liver is working.

Photosensitivity (sensitivity to sunlight): REZUROCK might cause you to become more sensitive to sunlight. If you have a reaction from the sun, talk to your healthcare professional.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Pregnancy and breastfeeding:

Female patients

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take REZUROCK if you are pregnant. It may harm your unborn baby.
- If you are able to become pregnant:
 - Your healthcare professional will do a pregnancy test before you start taking REZUROCK. This test must show that you are not pregnant.

- Avoid becoming pregnant while you are taking REZUROCK. Use effective birth control during your treatment and for at least 1 week after your last dose. Ask your healthcare professional about methods of birth control available to you.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with REZUROCK.
- Do not breastfeed while you are taking REZUROCK and for at least 1 week after your last dose.

Male patients

- Avoid fathering a child while you are taking REZUROCK.
- During your treatment with REZUROCK, use effective birth control each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using birth control for at least 3 months after your last dose.
- If, during your treatment with REZUROCK, your sexual partner becomes pregnant or thinks she may be pregnant, tell your healthcare professional right away.

Fertility in female and male patients:

REZUROCK may affect your fertility. Talk to your healthcare practitioner if you are planning on having children.

Tell your healthcare professional about all medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with REZUROCK:

- Medicines for bacterial infections such as rifampin.
- Medicines for excess stomach acid or ulcers, such as omeprazole and rabeprazole.
- Medicines for HIV treatment such as raltegravir.
- Medicines for sedation such as midazolam.
- Medicines for blood clots such as dabigatran.
- Medicines for lowering cholesterol levels in the blood such as rosuvastatin.

REZUROCK may affect the way other medicines work, and other medicines may affect the way REZUROCK works. Know the medicines you take. Keep a list of them to show your healthcare professionals when you get a new medicine.

How to take REZUROCK:

- Take exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take with food at the same time each day.

- Swallow REZUROCK tablets whole with a glass of water.
- Do not cut, crush, or chew REZUROCK tablets.

Usual dose:

Adults and children 12 years and over: Take one tablet (200 mg) per day.

Your healthcare professional may stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:

- experience serious side effects,
- your disease gets worse,
- are taking other medicines.

Overdose:

If you think you, or a person you are caring for, have taken too much REZUROCK, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

- If you miss a dose, take the missed tablet as soon as possible on the same day. Take the next dose at your usual time.
- Do not take an extra dose to make up for the missed dose.

What are the possible side effects from using REZUROCK?

These are not all the possible side effects you may feel when taking REZUROCK. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Infections,
- Tiredness or weakness,
- Nausea or vomiting,
- Difficulty swallowing,
- Diarrhea or constipation,
- Cough,
- Shortness of breath,
- Cold symptoms,
- Swelling,
- Bleeding,
- Stomach pain,
- Muscle, bone or joint pain,
- Muscle spasms,
- Headache,
- High blood pressure,
- Itchy skin, rash.

Your healthcare professional will do some tests before, during and after your treatment. These include blood tests to check your blood, kidney and liver health. More frequent tests might be needed.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Infections: fever and chills, fatigue, generally feeling unwell.		√	
COMMON			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness.		√	
Gastrointestinal problems: stomach pain, decreased appetite, diarrhoea, nausea, vomiting.		√	
Hypertension (high blood pressure): headache, shortness of breath, nosebleeds.		√	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, tiredness (may occur when you stand up from lying or sitting).		√	
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, tiredness, itchy skin.		√	
Pneumonia (infection in the lungs): high fever with chills, fast breathing, chest pain when you cough, cough which may produce phlegm, fatigue,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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nausea, vomiting or diarrhea, shortness of breath.			
Thrombocytopenia (low blood platelets): bleeding gums, nosebleeds, bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness.		√	
UNKNOWN FREQUENCY			
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

Note: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 15°C to 30°C in the original container.
- Keep REZUROCK in its original container. The REZUROCK bottle contains a desiccant packet to help keep your tablets dry (protect from moisture).
- Replace cap securely each time after opening. Do not remove desiccant (a small pack inside the bottle which protects the pills from moisture damage) from bottle.
- Keep out of the reach and sight of children.

- Ask your healthcare professional on how to throw away drugs you no longer use.

If you want more information about REZUROCK:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.sanofi.ca) or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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