

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Rezurock

Film-coated Tablets

Active ingredient

Each tablet contains belumosudil (as mesylate) 200 mg

Inactive and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED 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.

Therapeutic group: immunosuppressants.

What is chronic graft-versus-host disease?

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.

Rezurock works by blocking an enzyme called ROCK2 that is involved in how your immune system works.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to belumosudil or to any of the additional ingredients contained in the medicine (see Section 6).
- you are **pregnant**, since Rezurock can harm your unborn baby (see section "Pregnancy, breast-feeding and fertility").

Special warnings regarding use of the medicine

Before treatment with Rezurock, inform the doctor if:

- **you plan to become pregnant**, since Rezurock can harm your unborn baby (see section "Pregnancy, breast-feeding and fertility").
- **you 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").
- you have **kidney** problems.
- you have **liver** problems.
- you are taking other medicines (see section "Drug interactions").

Children and adolescents

Rezurock is not recommended for use in children under 12 years old. The safety and efficacy of Rezurock in children under 12 years old is not known.

Tests and follow-up

Perform blood tests before and during the course of treatment with Rezurock, including tests to monitor liver function.

Drug interactions

If you are taking, if you have recently taken, or you might take other medicines including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Rezurock may affect the way other preparations work, and other preparations may affect the way Rezurock works. Especially tell your doctor if you are taking any of the medicines in the table below as the doctor may need to change the dosage of these medicines or the dosage 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	

While you are taking Rezurock, you should never start a new medicine without checking first with the doctor. This includes prescription medicines, non-prescription medicines and herbal or alternative medicines. Keep a list of all the medicines you take to show the doctor and pharmacist when you get a new medicine.

Use of the medicine and food

Rezurock should be taken with food (see section 3).

Pregnancy, breast-feeding and fertility

Tell the 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 the 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 must avoid becoming pregnant for as long as 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 the doctor about how to use 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 machinery

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 experience these side effects.

Important information about some of the ingredients of the medicine

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 SHOULD YOU USE THE MEDICINE?

Rezurock will be prescribed to you by a doctor with experience of treating chronic graft-versus-host disease. Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage for adults and adolescents (12 years or over) is one tablet taken once daily orally at about the same time each day.

The doctor may increase the dosage of Rezurock if you are also taking certain medicines that can affect how Rezurock works.

Do not exceed the recommended dose.

Swallow the tablet whole with a glass of water with a meal. Do not cut, crush or chew Rezurock tablets.

The 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 too much Rezurock

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

If you forget to take Rezurock

If you missed 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 the 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.

Adhere to the treatment regimen as recommended by the doctor.

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 the doctor tells you to stop.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Rezurock may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

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

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

Additional side effects

Additional side effects include the following effects listed below. If these side effects become severe, tell the doctor.

Very common side effects (effects that occur **in more than 1 user in 10**):

- Extreme tiredness
- Feeling sick (nausea)

Common side effects (effects that occur **in up to 1 user in 10**):

- 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 level (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)
- Sudden shortness of breath or difficulty breathing (dyspnea)
- Cough
- High blood sugar level (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 creatine phosphokinase in the blood (a muscle enzyme)
- Increase in creatinine in the blood (a muscle waste product)
- Fever

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

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package/label. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25°C. Store in the original container to protect from moisture.

Tightly close the bottle after you take your dose.

The 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 the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Tablet core:

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

Tablet coating:

polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, yellow iron oxide.

What the medicine looks like and contents of the pack:

Oblong pale yellow tablets debossed with "KDM" on one side and "200" on the other side.

Rezurock is available in a plastic bottle with a child-resistant package.

The bottle contains 30 film-coated tablets.

License holder, importer and address: Sanofi Israel Ltd., Greenwork Park, P.O. box 47, Yakum.

Approved in September 2023

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1740137521

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