REZUROCK®
(belumosudil) tablets

A GUIDE TO YOUR CHRONIC GVHD TREATMENT with REZUROCK

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.

This booklet has been developed by Sanofi and is intended for patients who have been prescribed REZUROCK. This guide is intended to be used alongside the patient information leaflet and is not intended to replace the advice of your doctor.

GVHD=graft-versus-host disease

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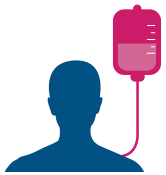
What is
CHRONIC GRAFT-VERSUS-HOST DISEASE (cGVHD)?

Learning about chronic GVHD can help you understand what's happening in your body and why. It can also help you understand **IMPORTANT TREATMENT PLAN DECISIONS FROM YOUR HEALTHCARE TEAM.**



GVHD is a potentially serious complication that can happen after an allogeneic blood stem cell transplant.

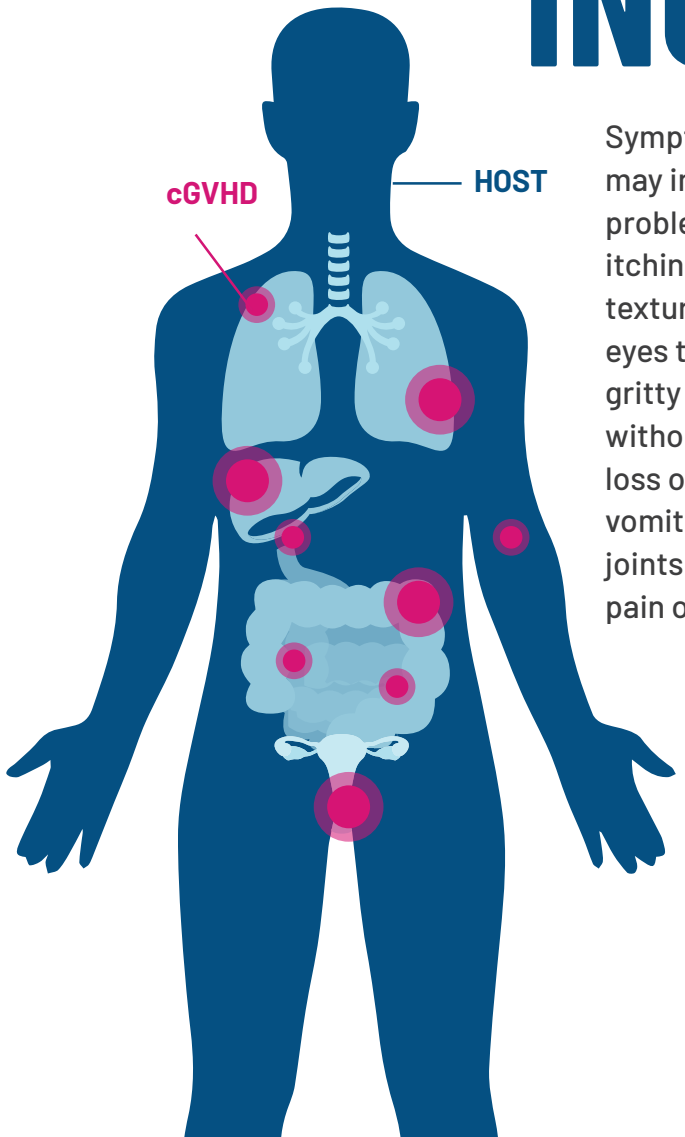
About 30-70% of the people who receive stem cells from a donor develop chronic GVHD.

Chronic GVHD occurs when the **stem cells from your donor (the graft)** start attacking **your body (the host)** because they see it as foreign. This usually starts 100 or more days after the transplant and can last a few months or a lifetime.

With chronic GVHD, almost any part of your body can be affected. It can range from being mild to severe and lead to different problems depending on which organs are affected.

Overall, this condition causes **inflammation** and **fibrosis (e.g., scarring of tissues)** in the body.

SYMPTOMS OF CHRONIC GVHD
INCLUDE



Symptoms of chronic GVHD may include the following: skin problems such as dryness, rash, itching, peeling, darkening, hard texture, and feeling tight; dry eyes that may have a burning or gritty feeling; dry mouth with or without mouth ulcers; diarrhoea, loss of appetite, stomach cramps, vomiting; pain in muscles and joints; infections; itchiness or pain of the vagina or penis.

How is REZUROCK used to
HELP TREAT cGVHD?

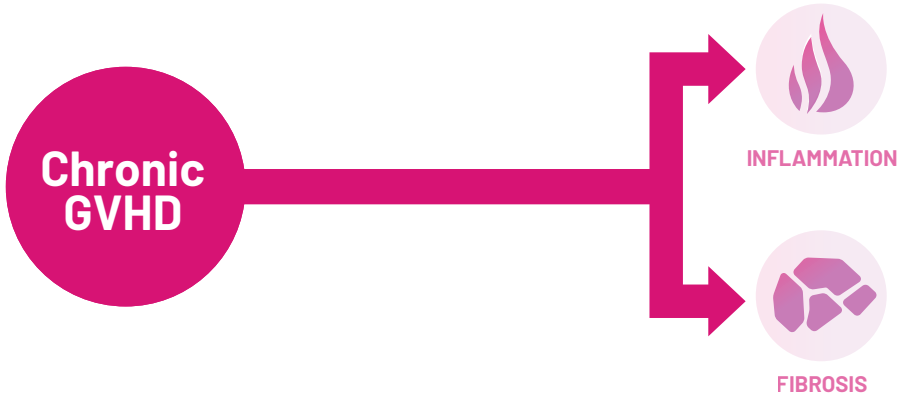
REZUROCK is a prescription medication used to treat adults and adolescents aged 12 years and older with chronic GVHD who have received at least two previous treatments.

Before you begin your treatment, your healthcare professional will do some tests to check your blood and liver health. These tests will continue during your treatment.

Be sure to talk to your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

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.



The time to response of REZUROCK will be different from other medications you may have taken. It is important that you take REZUROCK as long as your doctor has recommended.

How to
TAKE REZUROCK?

The REZUROCK 200-mg tablet is taken orally **once a day.**

Take REZUROCK with food
AT ABOUT THE SAME TIME EACH DAY.

Swallow the tablets whole with a glass of water.
DO NOT CUT, CRUSH, OR CHEW THE TABLET.

If you miss a dose, take the missed tablet as soon as possible on the same day if it is less than 12 hours since your dose was due. If it is more than 12 hours, do not take it. Take the next dose at your usual time. **DO NOT TAKE AN EXTRA DOSE** to make up for the missed dose.

- 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 are sick (vomit) after taking REZUROCK, do not take another tablet. Take your next dose at your regular time on the next day.

Your healthcare professional may decide to stop your treatment for a while or recommend that you stop completely. This may happen if you:

- Experience serious side effects
- Are taking other medicines, or
- Your disease gets worse

Take REZUROCK exactly as prescribed.
Check with your healthcare professional if you are unsure.

WHAT SIDE EFFECTS
should I be aware of?

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 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

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WHAT SIDE EFFECTS
should I be aware of?

- Upper respiratory tract infections (such as common cold, sinus infection)
- 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

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

If you experience any side effects not listed here, contact your healthcare professional.

Talk about any health conditions or problems you may have, including if you:

- Have kidney or liver problems
- Are taking other medicines

Pregnancy and BREASTFEEDING

Patients of childbearing potential

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.
- If you are able to become pregnant:
  - Your healthcare professional will do a pregnancy test before you start REZUROCK. This test must show that you are not pregnant.
  - Avoid becoming pregnant while taking REZUROCK. Use effective birth control during your treatment and for at least 1 week after your last dose.
  - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with REZUROCK.
- Do not breastfeed while you are taking REZUROCK and for at least 1 week after your last dose.

Patients assigned male at birth

- Avoid getting a sexual partner pregnant while you are taking REZUROCK.
- During your treatment with REZUROCK, use effective birth control each time you have sex with someone who is pregnant, may be pregnant, or could get pregnant. Continue using birth control for at least 1 week after your last dose.
- If, during treatment with REZUROCK, a sexual partner becomes pregnant or thinks they may be pregnant, tell your healthcare professional right away.

Ask your healthcare professional about methods of birth control available to you.

NOTES

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This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in the package leaflet

You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects or search for MHRA Yellow Card in the Google Play or Apple App Store.

Side-effects may also be reported directly to the Sanofi Drug Safety Department on 0800 090 2314 or by email to uk-drugsafety@sanofi.com.

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