

Your guide to ROZLYTREK[®] (entrectinib)

For patients who have been prescribed ROZLYTREK for the treatment of ROS1 fusion-positive (ROS1+), advanced non-small cell lung cancer (NSCLC)



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About this booklet

Your healthcare professional has given you this booklet to help you understand your treatment with ROZLYTREK® (entrectinib).

ROZLYTREK is a medicine used to treat advanced non-small cell lung cancer (NSCLC), where the tumours are 'ROS1 fusion-positive (ROS1+)'. Your doctor has already performed tests to find out that you have ROS1+ lung cancer (you can learn more about what this means on page 4 of this booklet).

In this booklet you will find answers to some of the common questions about ROS1+ NSCLC, and ROZLYTREK - including what it is, how it works, and how it's given. This booklet also contains important safety and side effect information, along with a list of useful resources for further information and support.

If you have questions, write them down in the space provided at the back of the booklet, to remind yourself to ask your doctor or nurse at your next appointment.

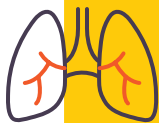
Please keep in mind that the booklet isn't designed to replace specific medical advice from your doctor or other healthcare professionals.

You can find out more about ROZLYTREK by visiting:

www.cancertreatments.co.nz

About ROS1+ advanced NSCLC

Non-small cell lung cancer, or NSCLC, is the most common form of lung cancer, occurring in around 85% of cases (the other type of lung cancer is small cell lung cancer, or SCLC). Your doctor has tested the cancer in your body to work out that you have NSCLC.



A small portion of people with NSCLC—about 2%—have an abnormality in their ROS1 gene.

Under normal circumstances, the ROS1 gene makes a protein which helps the cell know how to grow and function properly.

Your doctor has tested the tumour in your body and found out that the ROS1 gene has developed a gene 'fusion', so it is not working properly. A ROS1 gene fusion is where some of the DNA in the ROS1 gene has been mixed up and 'fused' to another gene. Because the DNA is not in the correct place, the cell cannot work properly.

- This results in the production of an abnormal ROS1 protein, which may cause the lung cancer in your body to grow and spread to other areas.
- This type of lung cancer is called ROS1 fusion-positive (ROS1+) advanced NSCLC.

A fusion in the ROS1 gene is not something you were born with. You cannot pass this on to future generations.



About ROZLYTREK

ROZLYTREK is a prescription medicine used to treat adults with ROS1+ non-small cell lung cancer (NSCLC). ROZLYTREK contains the active ingredient entrectinib. It belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents which are used to treat cancer. It is a type of **targeted therapy** called a 'TKI' (tyrosine kinase inhibitor) – it is **not** a chemotherapy or an immunotherapy. It is prescribed if your cancer:

- is ROS1+, and
- is advanced or has spread to another part of your body.



Your doctor performed a test to find out if you have ROS1+ NSCLC to help determine which treatments to prescribe for you.

ROZLYTREK may slow down or stop the cancer growing. It may also help to shrink the cancer.

Ask your doctor if you have any questions about why ROZLYTREK has been prescribed for you.

Before you start taking ROZLYTREK

Before taking ROZLYTREK, tell your doctor or pharmacist if you:



have allergies to any other medicines, foods, preservatives or dyes.



are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. ROZLYTREK and other medicines may interfere with each other.

These include:

- medicines used to treat cancer
- medicines used to prevent the body's immune system from rejecting a transplanted organ
- herbal medicines (for example, St. John's Wort)
- medicines used to treat AIDS/HIV
- medicines used to treat fungal infections
- medicines used to treat seizures or fits
- medicines used to treat tuberculosis and other infectious diseases.

These medicines may be affected by ROZLYTREK or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ROZLYTREK.

Always talk with your doctor if you have any questions about ROZLYTREK or other medicines you take.



have or have had any of the following medical conditions:

- heart problems or heart failure
- cannot tolerate or digest some sugars
- liver or kidney problems.



**are pregnant or plan to become pregnant
(or, if your partner is planning to become pregnant).**

- Your doctor can discuss with you the risks and benefits involved.
- ROZLYTREK may be harmful to an unborn baby when taken by a pregnant woman. You should not take ROZLYTREK while you are pregnant.
- Talk to your doctor about the right methods of contraception for you and your partner.



are breastfeeding or planning to breastfeed.

- It is not known if ROZLYTREK passes into breast milk. There is a possibility that your baby may be affected. It is not recommended that you breastfeed while taking ROZLYTREK.

If you have not told your doctor about any of the above, tell him/her before you start taking ROZLYTREK.

How you should take ROZLYTREK

ROZLYTREK is an oral treatment that you take once a day.

Your doctor will tell you how many capsules you need to take each day. This may depend on the cancer, whether you are taking any other medicines and whether you experience side effects.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information in this booklet.

The normal dose of ROZLYTREK for adults is three 200 mg capsules taken once daily (total dose 600 mg).



Take ROZLYTREK once a day, by mouth



Try taking it at about the same time each day



ROZLYTREK can be taken with or without food



ROZLYTREK should be swallowed whole



Do not open or dissolve ROZLYTREK capsules

How to store ROZLYTREK

Store at room temperature below 30°C.

Tips on remembering to take ROZLYTREK

Since ROZLYTREK is an oral medication, you can take it wherever you choose. It's important to remember to take ROZLYTREK once a day. It doesn't matter what time of day you choose to take ROZLYTREK, as long as it is the same time each day.

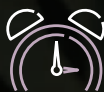
Below are some ways to help you make ROZLYTREK a part of your daily routine.



Take ROZLYTREK at the same time that you do other daily tasks, such as washing your face in the morning or when you eat breakfast.



Place your ROZLYTREK prescription bottle in a place where you will always see it.



Set an alarm on your clock or a reminder on your computer or mobile device.

What to do if you miss a dose, or take too much

If you miss a dose



You can take ROZLYTREK as soon as you remember, as long as it's more than 12 hours before your next dose. If it is less than 12 hours before your next dose, do not take the dose you missed – instead, just take ROZLYTREK at your next scheduled time. Do not take a double dose to make up for the dose that you missed.



If you vomit after a dose

ROZLYTREK may cause nausea. If you vomit immediately after taking a dose of ROZLYTREK, you may take the dose again. Otherwise, take ROZLYTREK at your next scheduled time.



If you take too much

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 764 766 or 0800 POISON) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

How long to take ROZLYTREK

Continue taking ROZLYTREK for as long as your doctor tells you. Everyone is different, so it is not known how long that will be. Do not stop taking ROZLYTREK without talking to your doctor first.

If you are not sure what to do, ask your doctor or pharmacist.

Other things to be aware of while taking ROZLYTREK



Be careful driving or operating machinery until you know how ROZLYTREK affects you.

This medicine may cause confusion, hallucinations, fainting, blurred vision or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.



Be careful what fruits and fruit juices you consume.

Grapefruit and grapefruit juice may increase the amount of ROZLYTREK in your blood to a harmful level – they should not be consumed while you are taking ROZLYTREK. Some other fruits and juices may also do this, and should be avoided.

These may include: star fruit, lemon, lime, seville orange, passionfruit, pomegranate, cranberry, kiwi, guava, pomelo, dragon fruit and rambutan.

- Tell all doctors, dentists, and pharmacists who treat you that you are taking ROZLYTREK.
- Keep all of your medical appointments so that your progress can be checked.
- Do not take ROZLYTREK to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
- Your doctor may still want to perform regular tests, such as blood tests to look at your white blood cell count, or to check how your liver and kidneys are functioning.

Possible side effects of ROZLYTREK

Like all medicines, ROZLYTREK may have some unwanted side effects. Sometimes they are serious; most of the time they are not. You may need medical attention to manage these side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you. Your doctor may be able to change your dose to stop this side effect happening for you.

Tiredness



- symptoms of anaemia (low levels of red blood cells or haemoglobin in the blood) such as tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- symptoms of low blood pressure such as dizziness and light-headedness



Pain

- pain including headache or head pain, or joint or muscle pain or pain or discomfort in limbs or bones

Gastrointestinal problems



- constipation
- diarrhoea
- feeling sick (nausea) or being sick (vomiting), or stomach pain
- difficulty in swallowing
- changes in taste
- weight gain
- loss of appetite
- dehydration



Infection

- fever
- lung infection
- urinary tract infection (symptoms include a strong frequent urge to urinate; cloudy, bloody or strong smelling urine; pain or burning sensation when urinating)



Abnormal senses

- an abnormal or unpleasant sense of touch
- blurred vision



Musculoskeletal problems

- numbness or weakness of the arms and legs
- loss of muscle coordination, being unsteady when walking
- muscle weakness
- bone fractures
- red, hot, stiff or swollen joints



Skin changes

- rash

Other side effects, not listed above, may also occur in some people. There are also side effects that can only be found when your doctor does tests, such as blood tests, to check your progress.

For a complete list of side effects, consult the Consumer Medicine Information which can be found at www.medsafe.govt.nz

Possible serious side effects

If you notice any of the following symptoms, tell your doctor immediately.



Heart failure

- signs of heart problems (heart failure) such as persistent coughing or wheezing, shortness of breath, and swelling in your legs or arms (fluid retention)



Abnormal heart rhythm

- feeling dizzy or light-headed, as this may be a sign of an abnormal heart rhythm



Confusion

- feeling confused, changes in mood, having memory problems or seeing things that are not there (hallucinations)



Fainting

- loss of consciousness or fainting

**Tell your doctor or pharmacist
if you notice anything that is
making you feel unwell.**

Taking care of yourself

A cancer diagnosis comes with many practical and emotional challenges. Below are some ideas that may help you cope and feel more in control.



Accept help: Don't be afraid to accept help from whānau and friends when it is offered to you, it allows them to show their support. It may be helpful to have one friend or whānau member coordinate offers of help, as well as to update others on your progress.



Be informed: Learning about what to expect can help you plan for changes and make you feel more secure. Take a look at the support organisations and what they can offer. Consider connecting with others in a similar situation through these organisations (see next page for details).



Focus on maintaining your health: Try to stay active and exercise regularly if you are able. This will depend on how well you feel and what you are used to. Studies have shown that regular exercise improves the quality of life of people with lung cancer. If you need to, aim to have several short rest periods/naps during the daytime, rather than one long rest.



Eat a balanced diet: To help your body cope with the cancer and treatment side effects, aim for a balanced and nutritious diet.



Contact your doctor or nurse if you have concerns: If you have any concerns or questions about your diagnosis or treatment, make sure to address these with your doctor or nurse.

Where to go for further support

As you receive treatment with ROZLYTREK, remember that you are not alone – the following groups know what you are going through and can offer you support and valuable information.

Cancer Society of New Zealand

The Cancer Society of New Zealand is the leading organisation dedicated to reducing the incidence of cancer and ensuring the best cancer care for everyone in New Zealand.

Website: www.cancernz.org.nz

Phone: **0800 226 237**

Lung Foundation New Zealand

The role of the Lung Foundation NZ is to ensure lung health is a priority for all New Zealanders. They aim to improve collaboration across the sector and deliver national lung health campaigns to promote and advocate for healthy lungs, including early detection of lung disease and lung cancer.

Website: www.lungfoundation.org.nz

The ROS1ders

The ROS1ders is a global group of patients and caregivers dealing with ROS1+ cancer. They strive to better understand outcomes for all ROS1+ cancers by supporting patients and caregivers, increasing awareness and education, accelerating research, and improving access to effective diagnosis and treatment.

Website: www.ros1cancer.com

Email: ros1cancer.patient@gmail.com

Talking with your doctor

Once you've started treatment with ROZLYTREK, it's important to ask your doctor or nurse any questions you may have about your treatment. Here are some suggested questions for your next appointment:



- **How will I know if ROZLYTREK is working?**
- **What is the best way to contact you if I experience any of the side effects?**
- **What should I know about the side effects I might experience?**
(Please see pages 12-14 for possible side effects with ROZLYTREK)
- **Do I have to make any lifestyle changes if I'm taking ROZLYTREK?**



ROZLYTREK® (entrectinib) 100mg/200mg capsules, is a **Prescription Medicine** used for the treatment of adult patients with ROS1-positive, locally advanced or metastatic (spreading) Non Small Cell Lung Cancer (NSCLC), and the treatment of adult and paediatric patients 12 years of age and older, with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive locally advanced or metastatic solid tumours, where other treatments have not worked or are not suitable for you.

Rozlytrek is an unfunded medicine for NSCLC and NTRK solid tumours. Ask your health professional about the cost of the medicine and other fees that may apply.

Use only as directed. If symptoms continue or you have side effects, see your healthcare professional. For more information about Rozlytrek:

- talk to your health professional; or
- visit medsafe.govt.nz for Rozlytrek Consumer Medicine Information; or
- visit cancertreatments.co.nz or call Roche on 0800 276 243.

Rozlytrek has risks and benefits.

Possible common side effects include: feeling tired, pain including headache or head pain or joint or muscle pain or pain or discomfort in limbs or bones, fever, constipation, diarrhoea, feeling sick (nausea) or being sick (vomiting) or stomach pain, difficulty in swallowing, changes in taste, an abnormal or unpleasant sense of touch, numbness or weakness of the arms and legs, loss of muscle coordination or being unsteady when walking, symptoms of anaemia such as tiredness/headaches/being short of breath when exercising/dizziness/looking pale, weight gain, loss of appetite, dehydration, muscle weakness, bone fractures, lung infection, urinary tract infection, blurred vision, rash, swelling or puffiness of the skin, disturbances in your sleep pattern, red, hot, stiff or swollen joints.

Do not use Rozlytrek if: you are allergic to entrectinib or any of the other ingredients in this medicine, or if you or your partner are pregnant or you are breastfeeding. Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Tell your doctor if: you have allergies to any other medicines/foods/preservatives/dyes, you have heart problems such as a condition called 'prolonged QT interval' or a condition called 'congestive heart failure' or 'heart failure', you have an inherited problem called 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption', liver or kidney problems, or if you are planning a pregnancy or plan to breastfeed. Tell your doctor if you are taking any other medicines.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following: signs of heart problems (heart failure) such as persistent coughing or wheezing, shortness of breath, and swelling in your legs or arms (fluid retention); feeling dizzy or light-headed as this may be a sign of an abnormal heart rhythm or low blood pressure; feeling confused, changes in mood, having memory problems or seeing things that are not there (hallucinations); loss of consciousness or fainting; symptoms of a condition called tumour lysis syndrome, including nausea or vomiting, muscle cramps or twitches, decreased urination, irritability, sudden uncontrolled fits (seizures).

This booklet is an educational initiative proudly sponsored by Roche.

This guide is intended as a resource for patients receiving treatment with ROZLYTREK. It is not intended as a substitute for advice from a qualified medical professional, nor is it considered a comprehensive and exhaustive source of information.

If you have any questions about your diagnosis or treatments, please speak to your healthcare professional.

For more information on ROZLYTREK visit www.cancertreatments.co.nz

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