

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking Rozlytrek?

Rozlytrek contains the active ingredient entrectinib. Rozlytrek is used to treat patients who have certain types of cancers - ROS1-positive lung cancer, or cancers with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. For more information, see Section [1. Why am I taking Rozlytrek?](#) in the full CMI.

2. What should I know before I take Rozlytrek?

Do not take Rozlytrek if you have ever had an allergic reaction to Rozlytrek or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take Rozlytrek?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Rozlytrek and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Rozlytrek?

- The recommended dosage for adults is 600 mg (3 x 200 mg capsules) taken by mouth once a day. Rozlytrek capsules should be swallowed whole with a glass of water and must not be opened or chewed.
- For children and adolescents, the dose will be calculated by the doctor based on the patient's weight and height.

More instructions can be found in Section [4. How do I take Rozlytrek?](#) in the full CMI.

5. What should I know while taking Rozlytrek?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Rozlytrek• Ensure you are using effective contraception (men and women). Even if you stop treatment you should continue to use effective contraception for at least 5 weeks after taking the last capsule if you are a woman and for at least 3 months after taking the last capsule if you are a man• Tell your doctor straight away if you become pregnant• Tell your doctor straight away if you experience any new or worsening symptoms or symptoms that concern you
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly, even if you feel well• Do not drink grapefruit juice or eat grapefruit during your treatment with Rozlytrek
Driving or using machines	<ul style="list-style-type: none">• Be careful driving and/or operating heavy machinery until you know how Rozlytrek affects you
Looking after your medicine	<ul style="list-style-type: none">• Keep Rozlytrek in the original bottle, tightly closed in a cool, dry place where children cannot access it. Rozlytrek should be stored at room temperature (below 30°C)• If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal

For more information, see Section [5. What should I know while taking Rozlytrek?](#) in the full CMI.

6. Are there any side effects?

Rozlytrek can cause side effects that you need to tell your doctor about straight away. Tell your doctor if you experience any side effects which concern you. Symptoms of serious side effects include persistent coughing or wheezing, shortness of breath, swelling in your legs or arms, feeling dizzy or light-headed, feeling confused, changes in mood, having memory problems or seeing things that are not there, loss of consciousness or fainting, symptoms of tumour lysis syndrome, including nausea or vomiting, muscle cramps or twitches, decreased urination, irritability, sudden uncontrolled fits (seizures). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ROZLYTREK (ROZ-LEE-TREK)

Active ingredient(s): *entrectinib*

This medicine has **provisional approval** in Australia for the treatment of adult and paediatric patients 12 years of age and older with solid tumours that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy.

The decision to approve this indication has been made on the basis of results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Rozlytrek. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Rozlytrek.**

Where to find information in this leaflet:

1. [Why am I taking Rozlytrek?](#)
2. [What should I know before I take Rozlytrek?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take Rozlytrek?](#)
5. [What should I know while taking Rozlytrek?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking Rozlytrek?

Rozlytrek contains the active ingredient entrectinib. Rozlytrek is a cancer medicine. Rozlytrek works by blocking the action of enzymes which have an alteration in them. This is due to the alteration in the NTRK or ROS1 genes that make them. The altered enzymes encourage the cancer cells to grow. Rozlytrek may slow down or stop the cancer growing. It may also help to shrink your cancer.

Rozlytrek is used in adults to treat a type of lung cancer called non-small cell lung cancer. It is used if your cancer:

- is 'ROS1-positive' – this means your cancer cells have an alteration in a gene called ROS1 and
- is advanced or has spread to another part of your body (metastatic)

Rozlytrek is also used to treat children (12 years and older), adolescents and adults with cancer that is 'NTRK fusion-positive'. This means that your cancer cells have an alteration in one of the NTRK genes. It is used if:

- your cancer is advanced or has spread to another part of your body (metastatic), and
- other treatments have not worked or are not suitable for you.

2. What should I know before I take Rozlytrek?

Warnings

Do not take Rozlytrek if:

- you are allergic to entrectinib, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine

Check with your doctor if you:

- have any other medical conditions such as heart problems (prolonged QT interval, congestive heart failure and/or heart failure - an inability for your heart to pump blood around your body);
- have inherited problems such as 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption'. Rozlytrek contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine
- have liver or kidney problems

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant or are breastfeeding.

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. **Do not take Rozlytrek while you are pregnant.**

If you are a woman who could become pregnant, use highly effective contraception (birth control) during

treatment, and for at least 5 weeks after taking the last capsule.

If you are the male partner of a woman who could become pregnant, use highly effective contraception during treatment, and for at least 3 months after taking the last capsule.

Talk to your doctor about the right methods of contraception for you and your partner.

Tell your doctor if you are planning to start breast-feeding.

Do not breast-feed if you are taking this medicine.

It is not known if entrectinib passes into breast milk. There is a possibility that your baby may be affected.

If you have not told your doctor about any of the above, tell them before you start taking Rozlytrek.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Rozlytrek and affect how it works. These include:

- nilotinib, topotecan, lapatinib and mitoxantrone used to treat cancer
- everolimus used to treat cancer or used to prevent the body's immune system from rejecting a transplanted organ
- sirolimus used to prevent the body's immune system from rejecting a transplanted organ
- St. John's Wort, a herbal medicine for depression
- ritonavir and saquinavir used to treat AIDS/HIV
- ketoconazole, itraconazole, voriconazole and posaconazole used to treat fungal infections
- phenytoin, carbamazepine and phenobarbital, anti-epileptics used to treat seizures or fits
- rifampicin and rifabutin 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Rozlytrek.

4. How do I take Rozlytrek?

How much to take

- For adults, the usual dose of Rozlytrek is three 200 mg capsules taken once a day (total dose 600 mg).
- For children and adolescents, the dose will be calculated by the doctor based on the patient's weight and height.

When to take Rozlytrek

- Take Rozlytrek once a day at about the same time each day.

How to take Rozlytrek

- Swallow the capsules whole with a full glass of water. Do not open or dissolve the capsules.
- The capsules can be taken with or without food.
- If you vomit immediately after taking a dose of Rozlytrek, take another dose.

If you forget to take Rozlytrek

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed

- If it is more than 12 hours until your next dose, take the missed dose as soon as you remember.
- If it is less than 12 hours until your next dose, do not take the missed dose. Then take your next dose at the usual time.

If you take too much Rozlytrek

If you think that you have taken too much Rozlytrek, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Rozlytrek?

Things you should do

Tell all doctors, dentists, and pharmacists who treat you that you are taking Rozlytrek.

Ensure you are using highly effective contraception. Even if you stop treatment, you should continue to use effective contraception for at least 5 weeks after taking the last capsule if you are a woman; and for at least 3 months after taking the last capsule if you are a man.

If you or your partner become pregnant while you are taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests and other tests from time to time to monitor your progress and check for side effects. If necessary, your doctor may decide to reduce your dose, temporarily interrupt your treatment or stop it altogether.

Remind any doctor, dentist or pharmacist you visit that you are taking Rozlytrek.

Things you should not do

- Do not take Rozlytrek to treat any other complaints unless your doctor tells you to
- Do not stop taking your medicine or changing the amount you take without checking with your doctor
- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not drink grapefruit juice or eat grapefruit during your treatment with Rozlytrek. It may increase the amount of the medicine in your blood to a harmful level.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Rozlytrek affects you.

Rozlytrek 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. Children should be careful when riding bicycles or climbing trees.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

- Store Rozlytrek at room temperature (below 30°C).
- Keep your capsules inside the original bottle and keep the bottle tightly closed until it is time to take them. If you take the capsules out of the bottle they may not keep well.
- Store Rozlytrek in a place where children cannot access it.
- Rozlytrek should be stored in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date, which is stated on the bottle and outer carton after "EXP". The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut-related:</p> <ul style="list-style-type: none"> • diarrhoea and/or constipation • nausea and/or vomiting • Stomach pain <p>Muscle-related:</p> <ul style="list-style-type: none"> • loss of muscle coordination, being unsteady when walking • muscle weakness and/or pain <p>Other:</p> <ul style="list-style-type: none"> • feeling tired • fever • difficulty in swallowing • changes in taste • an abnormal or unpleasant sense of touch • numbness or weakness of the arms and legs • symptoms of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale • weight gain • loss of appetite • dehydration • bone fractures • lung infection • urinary tract infection • blurred vision • rash • swelling or puffiness of the skin • disturbances in your sleep pattern • headache • pain including headache or head pain, joint pain or pain or discomfort in limbs or bones 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Heart-related:</p> <ul style="list-style-type: none"> • 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 • loss of consciousness or fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Symptoms of Tumour Lysis syndrome:</p> <ul style="list-style-type: none"> nausea or vomiting, muscle cramps or twitches, decreased urination, irritability, sudden uncontrolled fits (seizures). <p>Central nervous system/cognitive disorders:</p> <ul style="list-style-type: none"> feeling confused, changes in mood, having memory problems or seeing things that are not there (hallucinations) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Rozlytrek contains

Active ingredient (main ingredient)	entrectinib
Other ingredients (inactive ingredients)	Lactose Microcrystalline cellulose Tartaric acid Hypromellose Crospovidone Magnesium stearate Silicon dioxide The capsule shell contains: Hypromellose Titanium dioxide Iron oxide yellow (100 mg capsule only) Sunset yellow FCF (200 mg capsule only) The printing ink contains: Shellac

	Propylene glycol Strong ammonia solution Indigo carmine aluminium lake
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Do not take this medicine if you are allergic to any of these ingredients.

What Rozlytrek looks like

Rozlytrek 100 mg capsules are yellow with "ENT 100" imprinted in blue on the side. Rozlytrek 100 mg capsules are supplied in bottles of 30 capsules (AUST R 318003).

Rozlytrek 200 mg capsules are orange with "ENT 200" imprinted in blue on the side. Rozlytrek 200 mg capsules are supplied in bottles of 90 capsules (AUST R 318002).

Who distributes Rozlytrek

Roche Products Pty Limited
 ABN 70 000 132 865
 Level 8, 30 - 34 Hickson Road
 Sydney NSW 2000
 AUSTRALIA

Medical enquiries: 1800 233 950 or via www.medinfo.roche.com/australia

Please check with your pharmacist for the latest Consumer Medicine Information.

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