

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Rozlytrek® 100 mg hard capsules

Rozlytrek® 200 mg hard capsules

Entrectinib

Contains sugar (lactose) 65 mg

Read all of this leaflet carefully before you start taking Rozlytrek

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Rozlytrek® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Rozlytrek® is and what it is used for
2. What you need to know before you take Rozlytrek®
3. How to take Rozlytrek®
4. Possible side effects
5. How to store Rozlytrek®
6. Contents of the pack and other information

1. What Rozlytrek® is and what it is used for

What Rozlytrek is

Rozlytrek is a cancer medicine that contains the active substance entrectinib.

What Rozlytrek is used for

Rozlytrek is used to treat either:

- adults and children with solid tumour (cancer) in various parts of the body that is caused by a change in the neurotrophic tyrosine receptor kinase (NTRK) gene, or
- adults with a type of lung cancer called 'non-small cell lung cancer' (NSCLC) that is caused by a change in the ROS1 gene.

NTRK gene fusion-positive solid tumour cancer

It is used when:

- a test has shown that your cancer cells have a change in genes called 'NTRK' and has spread within the affected organ or to other organs in your body or if surgery to remove the cancer is likely to result in severe complications (see 'How Rozlytrek works' below), and
- you have not received treatment with medicines called NTRK inhibitors
- other treatments have not worked or are not suitable for you.

ROS1-positive non -small cell lung cancer (NSCLC)

It is used if your lung cancer:

- is 'ROS1-positive' – this means that your cancer cells have a change in a gene called 'ROS1' (see 'How Rozlytrek works' below),
- has spread to other parts of your body (metastatic), and
- you have not received treatment with medicines called ROS1 inhibitors.

How Rozlytrek works

Rozlytrek works by blocking the action of abnormal enzymes caused by a change in the NTRK or ROS1 genes that make them. The faulty enzymes encourage the cancer cells to grow.

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

2. What you need to know before you take Rozlytrek

Do not take Rozlytrek

- You are allergic to Rozlytrek (entrectinib) or
- You are allergic to any of the other ingredients of this medicine

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Rozlytrek if:

- you have recently experienced memory loss, confusion, hallucinations, or mental status changes
- you have a history of fractured bones, or conditions which may increase your risk of breaking bones, called 'osteoporosis' or 'osteopaenia'
- you take medication to lower the levels of uric acid in your blood
- you have heart failure (an inability for your heart to adequately pump blood to supply oxygen to the body) – signs can include cough, shortness of breath, and swelling in your legs or arms
- you have or had heart disorders, or a heart conduction problem called 'prolonged QTc interval' – this is shown on an 'electro cardiogram' (ECG), or low levels of electrolytes (potassium, magnesium, calcium or phosphorus) in your blood
- you have an inherited problem called 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption'.

Other medicines and Rozlytrek

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines). This is because Rozlytrek can affect the way some other medicines work. Also, some other medicines can affect the way Rozlytrek works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines for fungal infections (anti-fungals) – such as ketoconazole, itraconazole, voriconazole, posaconazole
- medicines to treat Acquired Immune Deficiency Syndrome (AIDS)/Human immunodeficiency virus (HIV) infection – such as ritonavir or saquinavir
- a herbal medicine for depression – St. John's Wort
- medicines to stop seizures or fits (anti-epileptics) – such as phenytoin, carbamazepine, or phenobarbital
- medicines for tuberculosis – such as rifampicin, rifabutin
- medicines to treat solid cancers and blood cancer – topotecan, lapatinib, mitoxantrone, apalutamide, methotrexate
- a medicine for inflammation of joints or joint autoimmune disease (rheumatoid arthritis) – methotrexate
- a medicine for migraine-type headaches – ergotamine
- a medicine for relief of severe pain – fentanyl
- a medicine for mental illness (psychoses) or involuntary movements and sounds, also called Tourette Syndrome – pimozide
- a medicine for irregular heart rate –quinidine
- medicines to prevent formation of blood clots – warfarin, dabigatran etexilate
- medicines for gastric reflux (heartburn) – cisapride, omeprazole
- medicines to reduce blood cholesterol – atorvastatin, pravastatin, rosuvastatin
- medicines to suppress your body's immune system, or prevent the body from rejecting an organ transplant – sirolimus, tacrolimus, cyclosporin,
- medicines for depression – paroxetine, fluvoxamine
- medicines to reduce blood sugar levels – repaglinide, tolbutamide

- medicines for high blood pressure – bosentan, felodipine, nifedipine, verapamil.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Rozlytrek.

Rozlytrek with food and drink

Do not drink grapefruit juice or eat grapefruit or Seville oranges during your treatment with Rozlytrek. It may increase the amount of the medicine in your blood to a harmful level.

Pregnancy, breast-feeding and fertility

Women and contraception

You should not become pregnant while taking this medicine because it could harm the baby. If you can become pregnant, you must use highly effective contraception while on treatment and for at least 5 weeks after stopping treatment.

It is not known if Rozlytrek can reduce the effect of birth control medicines (pills or implanted hormonal contraceptives). You should use another reliable method of birth control such as a barrier method (e.g. condom) so you do not become pregnant while you are taking Rozlytrek and for 5 weeks after you stop treatment.

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

Men and contraception

Your female partner should not become pregnant while you are taking this medicine because it could harm the baby. If your female partner can become pregnant, you must use highly effective contraception while on treatment and for at least 3 months after stopping treatment. Talk to your doctor about the right methods of contraception for you and your partner.

Pregnancy

- Do not take Rozlytrek if you are pregnant. This is because it may harm your baby.
- If you become pregnant when taking the medicine or during the 5 weeks after taking your last dose, tell your doctor straight away.

Breast-feeding

Do not breast-feed while taking this medicine. This is because it is not known if Rozlytrek can pass over into breast milk and could therefore harm your baby.

Driving and using machines

Rozlytrek may affect your ability to drive or use machines. Rozlytrek may cause you to:

- have blurred vision
- feel dizzy
- pass out (lose consciousness)
- feel tired
- have changes in your mental status, feel confused or see things that are not there (hallucinations).

If this happens, you should not drive, use a bicycle, or operate heavy machinery until your symptoms resolve. Talk to your doctor or pharmacist about whether it is okay for you to drive or use machines.

Rozlytrek contains:

- **lactose** (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- **sunset yellow FCF (E110) in 200 mg hard capsules only.** This is a colouring agent, which may cause allergic reactions.

3. How to take Rozlytrek

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Adults

- The recommended dose is 3 capsules of 200 mg once a day (total amount 600 mg).
- If you feel unwell, sometimes your doctor may lower your dose, stop treatment for a short time or stop treatment completely.

Children

- Rozlytrek can be used in children 12 years of age and older who can swallow capsules.
- Your doctor will work out the correct dose to use – this will depend on the height and weight of the child.

How to take

Take Rozlytrek by mouth – with or without food. Swallow each capsule whole. Do not open or dissolve the capsules since the contents of the capsule are very bitter.

If you vomit after taking Rozlytrek

If you vomit immediately after taking a dose of Rozlytrek, take another dose.

If you take more Rozlytrek than you should

If you take more Rozlytrek than you should, talk to a doctor or go to hospital straight away. Take the medicine pack and this leaflet with you.

If you forget to take Rozlytrek

- If your next dose is more than 12 hours later, take the missed dose as soon as you remember.
- If there are less than 12 hours until your next dose, do not take the missed dose. Then take your next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

If you stop taking Rozlytrek

Do not stop taking this medicine without talking to your doctor first. It is important to take Rozlytrek every day for as long as your doctor prescribes it for you.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

This medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Serious side effects

Tell your doctor straight away if you notice any of the following after having taken Rozlytrek. Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely:

- you have cough, shortness of breath, and swelling in your legs or arms (fluid retention). These can be signs of heart problems
- you feel confused, have changes in mood, memory problems or hallucinations (see things that are not there)
- you feel dizzy or light-headed, or feel your heart beating irregularly or fast, as this may be a sign of an abnormal heart rhythm
- you notice any joint pain, bone pain, deformities or changes in your ability to move

- you have kidney problems or arthritis, as this may be the result of high uric acid levels in your blood.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Very common: may affect more than 1 in 10 people:

- feeling tired
- constipation
- changes in taste
- feeling unsteady or dizzy
- swelling
- diarrhoea
- feeling sick
- abnormal sense of touch which feels like itching, tingling or burning sensation
- lack of enough red blood cells (anaemia)
- shortness of breath
- weight gain
- increased blood level of creatinine (a substance normally eliminated by the kidneys into the urine)
- pain including back pain, neck pain, musculoskeletal pain, pain in limbs
- vomiting
- cough
- fever
- muscle pain
- joint pain
- headache
- low blood pressure
- increased blood levels of certain liver enzymes (AST/ALT)
- abnormal unpleasant sensation in your arms or legs
- loss of muscle coordination, being unsteady when walking
- disturbance in normal sleep patterns
- lung infection
- urinary tract infection
- muscle weakness
- decreased appetite
- blurred vision
- rash
- decreased number of a type of white blood cell called neutrophils
- stomach pain
- inability to empty your bladder completely
- difficulty swallowing.

Common: may affect up to 1 in 10 people:

- mood disorders
- dehydration
- fluid in your lungs
- fainting
- increased sensitivity of the skin to sunlight

Uncommon: may affect less than 1 in 100 people:

- changes in certain chemicals in your blood caused by rapid breakdown of tumour cells, which may cause damage to organs, including the kidneys, heart, and liver.

Tell your doctor, pharmacist or nurse if you notice any of the side effects above.

Reporting of side effects

If you get side effects, talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Rozlytrek.

5. How to store Rozlytrek

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rozlytrek contains

The active substance is entrectinib.

Rozlytrek 100 mg: each capsule contains 100 mg entrectinib

Rozlytrek 200 mg: each capsule contains 200 mg entrectinib

The other ingredients are

- *Capsule content*: tartaric acid, lactose (see section 2 'Rozlytrek contains lactose'), hypromellose, croscopovidone, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- *Capsule shell*: hypromellose, titanium dioxide (E171), yellow iron oxide (E172; for Rozlytrek 100 mg capsule), sunset yellow FCF (E110; for Rozlytrek 200 mg capsule). See section 2 'Rozlytrek contains sunset yellow FCF (E110)'.
- *Printing ink*: shellac, propylene glycol, indigo carmine aluminium lake (E132).

What Rozlytrek looks like and contents of the pack

Rozlytrek 100 mg hard capsules are opaque yellow with ENT 100 imprinted in blue on the body.

Rozlytrek 200 mg hard capsules are opaque orange with ENT 200 imprinted in blue on the body.

The capsules are provided in bottles containing either:

- 30 hard capsules of Rozlytrek 100 mg, or
- 90 hard capsules of Rozlytrek 200 mg.

Holder of Certificate of Registration

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