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Rozlytrek® (active substance: entrectinib)

Temporary authorisation in Switzerland: 5 November 2020

Medicinal product (hard gelatin capsule) for the treatment of cancers that have a NTRK or ROS1 gene fusion in the tumour DNA

About the medicine

Rozlytrek is a cancer treatment containing the active substance entrectinib.

Therapy with Rozlytrek may be used for:

1- Adults and children aged 12 and older with solid tumours (new growths of cancer tissue) in which a neurotrophic tyrosine receptor kinase (NTRK) gene fusion has been identified

2- Adult patients with metastatic (spreading to other parts of the body) non-small cell lung cancer (NSCLC) in which a ROS1 gene fusion has been identified

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements. Medicinal products of this kind benefit from simplified authorisation conditions in Switzerland.

Mode of action

Tumours with NTRK or ROS1 gene fusions produce defective enzymes[1]. These defective enzymes[1] favour and control the growth of cancer cells, potentially leading to an uncontrolled proliferation of cancer cells.

Rozlytrek may slow or halt the growth of cancer by blocking the defective enzymes[1]. Rozlytrek may also contribute to shrinking the tumour.

Use

Rozlytrek, with the active substance entrectinib, is a prescription-only medicine and has been authorised as a hard gelatin capsule in the dosage strengths 100 mg and 200 mg.

Rozlytrek may only be used if the presence of a NTRK or ROS1 gene fusion has been determined using a molecular biological test.

The recommended dosage for adults is 3 capsules of 200 mg once a day (a total of 600 mg). The recommended dosage for children aged 12 and older who are able to swallow

a capsule is 300 mg/m^2 body surface area once daily.

The capsules must be swallowed whole either with or without food. They must not be opened or dissolved.

Efficacy

The efficacy of Rozlytrek was evaluated on the basis of data from 3 studies (ALKA, STARTRK-1 and STARTRK-2).

1. NTRK gene fusion

74 patients with a NTRK 1/2/3 gene fusion were included in the efficacy evaluation. 63.5% of the patients responded overall. The response rate was between 0 and 100% depending on the type of tumour. The median[2] duration of the response was 12.9 months.

Experience with Rozlytrek in children is very limited. The authorisation for treatment with Rozlytrek of children aged 12 and older is based on an extrapolation from the adult data and the pharmacokinetic[3] data from patients over 12 years of age (STARTTRK-NG).

2. ROS1-positive NSCLC

The studies of patients with a ROS1 gene fusion involved a total of 94 patients. Overall, 73.4% of the patients showed a response; the median[2] duration of the response was 16.5 months.

Precautions, undesirable effects & risks

Rozlytrek must not be used in those who are hypersensitive to the active substance or any of the excipients.

Cardiac function must be monitored regularly in patients with heart problems.

Rozlytrek may cause side effects, which must be reported to the doctor without delay. The most common side effects include: fatigue, constipation, modified sense of taste, dizziness, diarrhoea, nausea, anaemia, peripheral oedema, breathing problems, weight increase, elevated creatinine levels in the blood, pain, cognitive impairment, vomiting, cough, fever.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicine has been authorised

Tumours that contain NTRK or ROS1 gene fusions are rare.

Taking the possible risks into consideration, Swissmedic believes that giving Rozlytrek to patients with solid tumours that have a NTRK gene fusion is beneficial provided no other treatments are available or effective. Treatment brought about a reduction in tumour size in patients with metastatic non-small cell lung cancer in which a ROS1 gene fusion had been identified.

The medicinal product Rozlytrek was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials had been concluded at the time of authorisation.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Rozlytrek®

Information for patients (package leaflet): Information for patients Rozlytrek®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

[1]Enzymes: enzymes are proteins that act as biocatalysts, controlling and accelerating biochemical reactions in the body.

[2]Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

[3]Pharmacokinetics: Pharmacokinetics describes the totality of processes which a medicinal substance undergoes in the body. These include absorption of the pharmaceutically active substance, its distribution in the body, biochemical transformation and degradation, and excretion.

This information corresponds to that stated in the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.