▼ **VITRAKVI® (Larotrectinib) 20 mg/mL oral solution**
VITRAKVI® (Larotrectinib) 25 mg / 100 mg hard capsules
Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: *Oral solution:* Two bottles of 50ml oral solution. Each mL of oral solution contains larotrectinib sulfate equivalent to 20 mg of larotrectinib. *Hard capsules:* Each hard capsule contains larotrectinib sulfate equivalent to 25 mg or 100 mg larotrectinib. **Indication(s):** VITRAKVI as monotherapy is indicated for the treatment of adult and paediatric patients with solid tumours that display a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion, - who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and - who have no satisfactory treatment options. VITRAKVI has been authorised under a conditional approval scheme. **Posology & method of administration:** The presence of an NTRK gene fusion in a tumour specimen should be confirmed by a validated test prior to initiation of treatment with VITRAKVI. For oral use. VITRAKVI is available as a capsule or oral solution with equivalent oral bioavailability and may be used interchangeably. Do not take with grapefruit or grapefruit juice. *Oral solution*: The oral solution should be administered by mouth using an oral syringe of 1 mL or 5 mL volume or enterally by using a nasogastric feeding tube. Do not mix with feeding formulas. *Hard capsule*s: The capsules should be swallowed whole. **Adults:** The recommended dose is 100 mg VITRAKVI twice daily, until disease progression or until unacceptable toxicity occurs. **Children & adolescents:** Dosing is based on body surface area (BSA). The recommended dose in paediatric patients is 100 mg/m^2 VITRAKVI twice daily with a maximum of 100 mg per dose until disease progression or until unacceptable toxicity occurs. Refer to SmPC for recommended dose modifications for adverse reactions. Missed or vomited dose: take the next dose at the next scheduled time. **Hepatic impairment:** The starting dose of VITRAKVI should be reduced by 50% in patients with moderate (Child-Pugh B) to severe (Child-Pugh C) hepatic impairment. No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A). **Renal impairment:** No dose adjustment is required. **Elderly:** No dose adjustment is recommended. **Coadministration with strong CYP3A4 inhibitors:** Reduce VITRAKVI dose by 50%, refer to SmPC. **Contra-indications**: Hypersensitivity to the active substance or to any of the excipients. **Warnings & precautions:** VITRAKVI should only be used if there are no treatment options for which clinical benefit has been established, or where such treatment options have been exhausted (i.e., no satisfactory treatment options). Neurologic reactions including dizziness, gait disturbance and paraesthesia were reported in patients receiving VITRAKVI. Withholding, reducing, or discontinuing VITRAKVI dosing should be considered, depending on the severity and persistence of these symptoms. ALT, AST, ALP and bilirubin increase have been observed therefore liver function including ALT, AST, ALP and bilirubin should be monitored before the first dose, then every 2 weeks during the first month of treatment, then monthly for the next 6 months of treatment, then periodically during treatment. In patients who develop transaminase elevations, more frequent testing is needed. Withhold, modify dose or permanently discontinue VITRAKVI based on the severity, refer to SmPC. *Avoid co-administration with strong or moderate CYP3A inducers and strong P-gp inducers with VITRAKVI due to a risk of decreased exposure.* Women of childbearing potential must use highly effective contraception while taking VITRAKVI and for at least one month after stopping treatment. Males of reproductive potential with a nonpregnant woman partner of childbearing potential should be advised to use highly effective contraception during treatment with VITRAKVI and for at least one month after the final dose. VITRAKVI 20mg/mL Two bottles, of 50ml oral solution contains sodium benzoate. **Interactions:** For the effects of other agents on the action of VITRAKVI (e.g CYP3A, P-gp and BCRP inhibitors; and CYP3A and P-gp inducers) and the action of VITRAKVI on other agents (CYP3A substrates, CYP2B6 substrates, other transporter substrates and PXR regulated enzymes) refer to SmPC. Unknown if VITRAKVI interacts with hormonal contraceptives, advise to use additional barrier method and continue for 1 month after final dose. **Pregnancy & lactation:** Avoid the use of VITRAKVI during pregnancy. Breast-feeding should be discontinued during treatment with VITRAKVI and for 3 days following the final dose. **Effects on ability to drive and use of machines**: Patients should be advised not to drive and use machines, until they are reasonably certain VITRAKVI therapy does not affect them adversely. **Undesirable effects**: *Very common*: anaemia#, neutrophil count decreased (neutropenia)*, leukocyte count decreased (leukopenia)*, dizziness#, nausea#, constipation, vomiting#, diarrhoea#, myalgia#, fatigue#, alanine aminotransferase (ALT) increased*, aspartate aminotransferase (AST) increased*, weight increased (abnormal weight gain)#. *Common:* gait disturbance#, paraesthesia#, dysgeusia, platelet count decreased*, muscular weakness*, blood alkaline phosphatase increased*. *Frequency unknown:* liver injury*. *Serious: cf. CI/W&P*; in addition, the above undesirable effects may also be serious. Grade 3/4 reactions were more frequent in patients aged < 6 years and occurred in 69% of those aged birth to < 3 months and in 48% of patients ≥3 months to <6 years. *Grade 4 reported. #Grade 3 reported. Physicians should consult the SmPC in relation to other side effects. **Overdose:** In the event of overdose, physicians should follow general supportive measures and treat symptomatically. **Special Precautions for Storage**: Oral solution: Store in a refrigerator (2 °C - 8 °C). Do not freeze. *Hard capsules*: None. **Legal Category:** POM **Package Quantities & Basic NHS Costs:** *Oral solution* Two 50 mL glass bottles £5,000; *Hard capsules* one bottle of 56 x 25 mg hard capsules £3,500; one bottle of 56 x 100 mg hard capsules £14,000. MA Number(s): EU/1/19/1385/001-003 and PLGB 00010/0741-0743. **Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation: September 2023**
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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax: 0118 206 3703, Email: pvuk@bayer.com