

Celsentri maraviroc 25mg, 75mg,150mg and 300mg tablets, oral solution 20mg/mL.

Prescribing Information

See Summary of Product Characteristics (SmPC) before prescribing.

Indication: HIV with only CCR5-tropic HIV-1 detectable in treatment-experienced adults, adolescents and children of 2 years of age and older and weighing at least 10 kg as part of combination therapy. **Dosage and administration:** CCR5 tropism status must be confirmed shortly before starting Celsentri. *Adults:* Orally: Celsentri 150 mg, 300 mg or 600 mg twice daily depending on interactions with co-administered antiretroviral therapy and other medicinal products (see SmPC). *Children from 2 years of age and weighing at least 10kg:* dose according to body weight and do not exceed the recommended adult dose. Use oral solution (20m/mL) if a child is unable to reliably swallow tablets. Celsentri can be taken with or without food. *Elderly:* Limited data in 65+ yrs. *Renal impairment:* Caution and adjust Celsentri dosage interval in adult patients with creatinine clearance < 80ml/min taking potent CYP3A4 inhibitors. No data in children. *Hepatic impairment:* Caution due to lack of data. **Contraindications:** hypersensitivity to any ingredient (including peanut or soya). **Special warnings and precautions:** Risk of severe skin & hypersensitivity reactions. Discontinue Celsentri and other suspect agents immediately if suspected. Not recommended in treatment naïve patients. Adjust Celsentri dose and/or dose interval when co-administered with interacting medication. Risk of dose-related dizziness: caution patients with a history of postural hypotension or receiving medicines known to lower blood pressure. Risks of osteonecrosis, immune reactivation syndrome, potential effect on immunity. Use Celsentri with

caution in patients with severe cardiovascular disease, severe renal insufficiency, reduced hepatic function, significant underlying liver disorders, hepatitis B/C co-infection or renal impairment due to lack of data. Consider discontinuation of Celsentri in any patient with signs or symptoms of acute hepatitis. Celsentri contains soya lecithin.

Interactions: Celsentri is a substrate of (but does not inhibit or induce) CYP3A4. See SmPC for dose adjustment guidance when co-administering Celsentri with CYP3A4 inhibitors and/or inducers. Use with fosamprenavir/ritonavir, St John's Wort or two inducers (e.g. rifampicin + efavirenz) not recommended. Caution with dabigatran etexilate.

Pregnancy and lactation: Not recommended. **Do not breast-feed.** **Side effects:** See SmPC for full details. Nausea, diarrhoea, fatigue, headache, abdominal pain, flatulence, rash, asthenia, insomnia, depression, anorexia, anaemia and increased levels of alanine aminotransferase and aspartate. Rarely, neoplasms, blood disorders, cardiac disorders, hepatotoxicity, Stevens Johnson syndrome, toxic epidermal necrolysis, muscle atrophy. **Basic NHS costs:** 25mg: 120 tablets £147.09; 75mg: 120 tablets £441.27; 150mg: 60 tablets £519.14; 300mg: 60 tablets £519.14; Oral Solution 20mg/mL: 235mL £230.44. **MA numbers:** 25mg tablets EU/1/07/418/011; 75mg tablets EU/1/07/418/012; 150mg tablets EU/1/07/418/003; 300mg tablets EU/1/07/418/008; Oral Solution 20mg/mL EU/1/07/418/013. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands.

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POM

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Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.