Vocabria▼ cabotegravir 30mg tablets and 600mg prolonged-release suspension for injection, Edurant rilpivirine 25mg tablets and Rekambys▼ rilpivirine 900mg prolonged-release suspension for injection

Prescribing Information – GB

See Summaries of Product Characteristics (SmPCs) before prescribing

Adverse events should be reported. For the UK, reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/** or search for **MHRA Yellowcard** in the **Google Play or Apple App store**. Adverse events should also be reported to GSK via the **GSK Reporting Tool** or on 0800 221441.

Indication: Cabotegravir in combination with rilpivirine for treatment of HIV-1 in adults and adolescents (at least 12 years of age and weighing at least 35 kg), who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior failure with agents of NNRTI and INI class. **Dosing:** *Adults and adolescents (at least 12 years of age and weighing at least 35 kg)* carefully selected who agree to the injection schedule and are counselled about the importance of adherence. An oral lead in prior to the initiation of injections can be used to assess tolerability or proceed directly to injections. For oral lead in: Prior to injections, once-daily oral dosing of cabotegravir and rilpivirine for approximately 1 month (at least 28 days) with food. Initiation injections: Direct to injection months 1 and 2, or following oral lead in: months 2 and 3 (final day of oral lead-in therapy). Separate intramuscular (gluteal) 3mL initiation injections of Vocabria and Rekambys. Continuation injections: Two months after the final initiation injections and every 2 months thereafter. Separate intramuscular (gluteal) 3mL injections of Vocabria and Rekambys. Injections may be administered up to 7 days before or after the due date. See SmPCs for advice outside this window or missed injections. Caution in severe renal impairment or moderate hepatic impairment. Not recommended in severe hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient. Coadministration with rifampicin, rifapentine, rifabutin, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, systemic dexamethasone (except single dose), St John's Wort. PPIs (oral rilpivirine). **Special warnings/precautions:** If discontinued, adopt a fully suppressive antiretroviral regimen no later than when the next injection would have been due. If virologic failure is suspected an alternative regimen should be adopted as soon as possible**.** Residual concentrations may remain for prolonged periods after discontinuation. Increased risk of failure associated with 2 or more of: archived rilpivirine resistance mutations, BMI ≥30 kg/m^2 or HIV-1 A6/A1 subtype. Caution if uncertain treatment history without pre-treatment resistance analyses, if BMI ≥30 kg/m^2, or HIV-1 A6/A1 subtype. Hypersensitivity reactions. Rare, serious post-injection reactions from accidental IV administration. Hepatotoxicity (monitor LFTs). Not recommended in hepatitis B. Limited data in hepatitis C (monitor LFTs). Opportunistic infections. Immune reactivation syndrome. QTc prolongation at supratherapeutic doses – caution with medicines associated with Torsade de Pointes. Not to be used with other antiretrovirals for HIV. Caution with narrow therapeutic index OAT1/3 substrates, e.g. methotrexate. If macrolide antibiotics required, consider azithromycin. Caution with oral treatments and H_2 antagonists and antacids. See SmPCs for full list of interactions. **Pregnancy/breast feeding:** Not recommended. **Side effects:** See SmPCs for full details. Injection site reactions (generally mild/moderate) including cellulitis and abscess formation (uncommon), headache, pyrexia (mostly reported within one week of injection), depression, depressed mood, anxiety, abnormal dreams, insomnia/sleep disorder, somnolence, dizziness, suicidal ideation/suicide attempt (uncommon – particularly in patients with a history of depression or psychiatric illness), dry mouth, decreased appetite, nausea, vomiting, abdominal pain/discomfort, flatulence, diarrhoea, fatigue, asthaenia, malaise, rash, myalgia, weight increase, hypersensitivity, angioedema, urticaria, hepatotoxicity, pancreatitis, increased transaminases, increased bilirubin, decreases in white blood cells, haemoglobin and platelet count, increases in cholesterol, triglycerides, pancreatic amylase, and lipase. **Basic NHS costs:** *Vocabria*: £638.57 for 30 tablets (PLGB 35728/0055), £1197.02 per 600mg vial (PLGB 35728/0057); *Edurant:* £200.27 for 30 tablets

(PLGB 00242/0678); *Rekambys* £440.47 per 900mg vial (PLGB 00242/0726). **MA holders:** *Vocabria* - ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS; *Edurant and Rekambys* - Janssen-Cilag Ltd, 50 - 100 Holmers Farm Way, High Wycombe, Bucks, HP12 4EG. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

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