Abbreviated Prescribing Information

Vocabria (cabotegravir) 600 mg prolonged-release suspension for injection
Rekambys (rilpivirine) 900 mg prolonged-release suspension for injection.
See Summaries of Product Characteristics (SmPC) before prescribing.
Presentation: Vocabria vials contain 600 mg cabotegravir in 3mL. Rekambys vials contain 900 mg rilpivirine in 3mL. **Indication:** Vocabria and Rekambys in combination are indicated for the treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class. **Dosing:** Therapy should be prescribed by a physician experienced in the management of HIV infection. Prior to starting Vocabria and Rekambys, healthcare professionals should have carefully selected patients who agree to the required injection schedule and counsel patients about the importance of adherence to scheduled dosing visits. Following discontinuation of Vocabria and rilpivirine injection, it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than two months after the final injection of Vocabria and rilpivirine. The healthcare provider and patient may decide to use cabotegravir tablets as an oral lead-in prior to the initiation of Vocabria and Rekambys injection to assess tolerability to cabotegravir or may proceed directly to Vocabria and Rekambys injections .If oral lead-in is used: Prior to the initiation of injections, oral cabotegravir together with oral rilpivirine should be taken for approximately one month (at least 28 days) to assess tolerability to cabotegravir and rilpivirine. One cabotegravir 30 mg tablet should be taken with one rilpivirine 25 mg tablet, once daily. When administered with rilpivirine, cabotegravir tablets should be taken with a meal. Initiation injection: On the final day of current antiviral therapy or oral-lead in therapy, the recommended initial dose is a single intramuscular injection of Vocabria 600 mg injection and rilpivirine 900 mg administered at separate gluteal injection sites at the same visit and at a second date one month later. Vocabria injection should be administered by a healthcare professional. For instructions on Vocabria administration, see "Instructions for Use" in the package leaflet. Carefully follow these instructions when preparing the suspension for injection to avoid leakage. After the second Vocabria 600 mg injection and rilpivirine 900 mg injection the continuation injection dose is Vocabria 600mg injection and rilpivirine 900 mg injection administered at separate gluteal injection sites at the same visit every two months. Patients may be given injections up to 7 days before or after the date of the two monthly injection schedule. See SmPC for advice on missed injections. No dose adjustment requirement in the elderly. No dose adjustment is required in patients with mild to moderate renal impairment. In patients with severe renal impairment or end stage renal disease the combination with a strong CYP3A inhibitor should only be used if the benefit outweighs the risk. No dose adjustment is required in mild or moderate hepatic impairment (Child-Pugh score A or B), but caution is advised in patients with moderate hepatic impairment. Not recommended in patients with severe hepatic impairment (Child-Pugh score C). **Contraindications:** Hypersensitivity to any ingredient. Co-administration with rifampicin, rifapentine, rifabutin, carbamazepine, oxcarbazepine, phenytoin, phenobarbital, dexamethasone (except as a single dose treatment) or St John's Wort. **Special warnings/ precautions**: To minimise the risk of developing viral resistance it is essential to adopt an alternative, fully suppressive antiretroviral regimen no later than two months after the final injection of Vocabria and Rekambys. Consider the prolonged release characteristics of Vocabria and Rekambys injections (up to 4 years) when discontinuing. Multivariable analyses indicate that a combination of at least 2 of the following baseline factors may be associated with an increased risk of virological failure: archived rilpivirine resistance mutations, HIV-1 subtype A6/A1, or BMI ≥30 kg/m2. Available data suggest that virologic failure occurs more often when these patients are treated according to the every 2 month dosing regimen as compared to the monthly dosing regimen. In patients with an incomplete or uncertain treatment history without pre-treatment resistance analyses, caution is warranted in the presence of either BMI ≥30 kg/m2 or HIV-1 A6/A1 subtype. Risk of hypersensitivity reactions including dyspnoea, agitation, abdominal cramping, flushing, sweating, oral numbness and changes in blood pressure. Discontinue Vocabria and Rekambys and other suspect agents immediately if suspected. Use with caution when co-administered with products with a known risk of Torsade de Pointes. Monitor LFTs and discontinue if hepatotoxicity suspected. Not recommended in patients with HBV co-infection. Monitor LFTs in patients with HCV co-infection. Do not administer Vocabria and Rekambys with other antiretroviral products. In HIV-infected patients with severe immune deficiency at the time of institution of combination antiretroviral therapy, an inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise for example cytomegalovirus retinitis, generalised and/or focal mycobacterial infections, and Pneumocystis jirovecii pneumonia. Any inflammatory symptoms should be evaluated, and treatment instituted when necessary. Autoimmune disorders (Graves' disease and autoimmune hepatitis) have also been reported to occur in the setting of immune reconstitution. Caution when co-dosing with narrow therapeutic index OAT1/3 substrate drugs. **Fertility, pregnancy and lactation:** Human fertility: No data. Animal fertility studies indicate no effects. Pregnancy: Not recommended unless expected benefit justifies the potential risk to the foetus. If used viral load should be monitored closely. Do not breast-feed. **Side effects:** Very common (≥1/10): Headache, injection site reactions (pain and discomfort, nodule, induration), increased total cholesterol (fasted), increased LDL cholesterol (fasted), increased pancreatic amylase, pyrexia (majority of cases reported within one week of injection. Common (≥1/100 to <1/10): Depression, anxiety, abnormal dreams,

insomnia, sleep disorder, dizziness, GIT symptoms, rash, myalgia, injection site reactions (swelling, erythema, pruritus, bruising, warmth, haematoma), fatigue, asthenia, malaise, weight increased, decreased white blood cell count, decreased haemoglobin, decreased platelet count, decreased appetite, increased triglycerides (fasted), abdominal discomfort, dry mouth, increased lipase. Uncommon (≥1/1,000 to <1/100): Hypersensitivity, immune reactivation syndrome, suicide attempt, suicidal ideation (particularly in patients with a pre-existing history of psychiatric illness), somnolence, vasovagal reactions (in response to injections), hepatoxicity, urticaria, angioedema, injection site reactions (cellulitis, abscess, anaesthesia, haemorrhage, discolouration), transaminase increased, bilirubin increased. **Vocabria: MA Nr:** EU/1/20/1481/003. **Vocabria MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. **Rekambys MA Nr**: EU/1/120/1482/002. **Rekambys MA holder:** Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **Legal Category:** POM A. **Date of preparation of API:** February 2024. **Code:** PI-12264. Further information available from GlaxoSmithKline, 12 Riverwalk, Citywest, Business Campus, Dublin 24. Tel: 01-4955000.

Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.