Rukobia▼ (fostemsavir) 600mg prolonged release tablets Prescribing Information

Please refer to Prescribing Information as follows:

- **England, Scotland & Wales (GB)**
- **Northern Ireland (NI) – see page 2**

Prescribing Information – England, Scotland & Wales (GB)

Rukobia▼ fostemsavir 600mg prolonged release tablets
See Summary of Product Characteristics (SmPC) before prescribing

Indication: Adults with multidrug resistant HIV-1 infection (in combination with other ARVs) for whom it is otherwise not possible to construct a suppressive antiviral regimen. **Dosing:** *Adults (over 18 years)*: 600 mg twice daily, with or without food, swallowed whole with water – do not crush, chew or split the tablets. *Elderly:* No dosage adjustment required. (Limited data in 65+ yrs). No dosage adjustment required in renal or hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with strong CYP3A inducers including, but not limited to: carbamazepine, phenytoin, mitotane, enzalutamide, rifampicin and St John's Wort. **Special warnings and precautions:** See SmPC for full details. Rukobia is not recommended for treatment of infections due to HIV-1 Group M subtype CRF01_AE strains. Risks of immune reconstitution inflammatory syndrome, opportunistic infections, osteonecrosis. Use with caution in patients with a history of QT interval prolongation, when co-administered with a medicine with a known risk of Torsade de Pointes (e.g. amiodarone, disopyramide, ibutilide, procainamide, quinidine, or sotalol) or in patients with relevant pre-existing cardiac disease. Elderly patients may be more susceptible to drug-induced QT interval prolongation. Monitor LFTs in hepatitis B and/or C co-infection. Co-administration with elbasvir/grazoprevir is not recommended. Use with caution when co-administered with statins that are substrates for OATP1B1/3 or BCRP, and consider dose modifications. Doses of co-administered oestrogen-based therapies should not exceed 30 µg/day of ethinyl oestradiol. Caution is advised particularly in patients with additional risk factors for thromboembolic events. The recommended dose of co-administered tenofovir alafenamide (TAF) is 10mg. **Pregnancy/lactation:** Avoid use of Rukobia during pregnancy as data are limited. Do not breast-feed. **Side effects:** See SmPC for full details. Diarrhoea, headache, nausea, rash, abdominal pain, vomiting, immune reconstitution inflammatory syndrome, insomnia, dizziness, somnolence, dysgeusia, QT prolongation, dyspepsia, flatulence, pruritus, myalgia, fatigue, and increases in transaminases, creatinine and CPK. **Basic NHS costs:** £2,900 for 60 tablets. **MA number:** PLGB 35728/0058. **MA holder:** ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. Further information available from: customercontactuk@gsk.com Freephone 0800 221 441.

POM

Date of approval: September 2021 PI-8575v2

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 221441.

Prescribing Information – Northern Ireland

Rukobia▼ fostemsavir 600mg prolonged release tablets
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POM

Date of approval: September 2021 PI-8574v2

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 221441.

Date of approval of combined PI: September 2021 PI-8576v2