Rukobia
(fostemsavir) extended-release tablets · 600 mg

Do you care for patients like these in your practice?

People living with MDR HIV-1 who may have complex regimens that include entry inhibitors or twice-daily dolutegravir or darunavir

Did you know there are opportunities to optimize their ARV regimens if their regimens are no longer working?

ARV=antiretroviral; HIV-1=human immunodeficiency virus type-1; MDR=multidrug-resistant.
Not actual patients.

INDICATION

RUKOBIA, in combination with other antiretrovirals (ARVs), is indicated to treat HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current ARV regimen due to resistance, intolerance, or safety considerations.

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with previous hypersensitivity to fostemsavir or any of the components of RUKOBIA.
- Do not use RUKOBIA in patients receiving strong cytochrome P450 (CYP)3A inducers, including but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, and St John's wort *(Hypericum perforatum)*.

Warnings and precautions

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of RUKOBIA.

QTc Prolongation with Higher than Recommended Dosages: RUKOBIA at 2,400 mg twice daily has been shown to significantly prolong the QTc interval of the electrocardiogram. Use RUKOBIA with caution in patients with a history of QTc interval prolongation or in patients with relevant pre-existing cardiac disease or who are taking drugs with a known risk of Torsade de Pointes. Elderly patients may be more susceptible to drug-induced QT interval prolongation.

Elevations in Hepatic Transaminases in Patients with Hepatitis B or C Virus Co-infection:

- Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C co-infection.
- Diligence should be applied in initiating or maintaining effective hepatitis B therapy when starting RUKOBIA in patients co-infected with hepatitis B.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of RUKOBIA and other drugs may occur (see Contraindications and Drug Interactions).

Please see additional Important Safety Information on page 2.
Please see full Prescribing Information for RUKOBIA.

Your patients living with MDR HIV-1 whose current regimen is no longer successful may benefit from a change

Re-evaluate current regimen

If your patients living with MDR HIV-1 are no longer successful on their current regimen due to any of the clinical factors below, they may be appropriate for RUKOBIA.

Resistance

Is **drug resistance** limiting efficacy?

OR

Intolerance

Is their treatment regimen unsuccessful due to **tolerability issues**?

OR

Safety concerns

Are **drug-drug interactions** or new or existing **comorbidities** causing safety concerns?

Prescribe RUKOBIA as part of optimized ARV regimens

Explore how RUKOBIA works differently as a first-in-class attachment inhibitor that directly targets HIV-1 to protect CD4+ T-cells

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- The most common adverse reaction (all grades, randomized cohort) observed in ≥5% of subjects was nausea (10%).
- 81% of adverse reactions reported with RUKOBIA were mild or moderate in severity.

Drug interactions

- See the full Prescribing Information for RUKOBIA for a complete list of significant drug interactions.
- Temsavir may increase plasma concentrations of grazoprevir and voxilaprevir. Use an alternative hepatitis C virus regimen if possible.
- Use the lowest possible starting dose for statins and monitor for statin-associated adverse events.
- Patients receiving RUKOBIA should not take doses of estrogen-based therapies, including oral contraceptives, that contain more than 30 mcg/day of ethinyl estradiol. Caution is advised particularly in patients with additional risk factors for thromboembolic events.

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of RUKOBIA during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance, and adverse reactions in a breastfed infant.

Please see additional Important Safety Information on page 1.
Please see full Prescribing Information for RUKOBIA.

ViiV Healthcare

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