Splitting or Crushing *Rukobia* Tablets

Summary

- *Rukobia* (fostemsavir [FTR]) is a film-coated, non-scored, extended-release/prolonged-release (ER/PR) tablet for oral administration.[1] The tablets are designed to deliver the prolonged release profile and are required to maintain a safe and efficacious plasma profile.
- The efficacy, safety, stability, pharmacokinetic, and physiochemical properties of FTR tablets when split or crushed prior to administration have not been evaluated.[1] FTR is only recommended at a dose of 600 mg twice-daily with or without food.[2] To ensure administration of the entire dose of an FTR tablet, it should be swallowed whole, and should not be chewed, crushed or split.
- Important safety information is found in the attached Prescribing Information.

To access additional scientific information related to ViiV Healthcare medicines, visit the ViiV US Medical Portal at viivhcmedinfo.com.

CHARACTERISTICS AND ADMINISTRATION OF FTR TABLETS

FTR is a film-coated, non-scored, ER/PR tablet intended for oral administration, with or without food.[1,2] Following administration, fostemsavir tromethamine (the active ingredient) slowly diffuses from the extended release polymer matrix of the tablet core and is hydrolysed to temsavir and absorbed.[1] The tablets are designed to deliver the prolonged release profile and are required to maintain a plasma profile that maximizes efficacy and safety. The tablet formulation is a key part of this control.

FTR tablets are beige, biconvex, oval shaped, film-coated tablets (approximately 10.2 mm x 19.0 mm) with "SV 1V7" debossed on one side and plain on the other side.[1] An individual FTR 600 mg tablet weighs approximately 1180 mg.

SPLITTING OR CRUSHING FTR TABLETS

The efficacy, safety, stability, pharmacokinetic and physiochemical properties of FTR tablets that have been split or crushed prior to administration, has not been evaluated.[1] FTR tablets, 600mg are labelled 'Swallow whole, do not chew'. This is in order to:

- Ensure administration of the entire dose of an FTR tablet, with the required rate of FTR release.[1] The formulation design selection was based on the need for a sustained release profile to achieve appropriate trough levels for the active moiety temsavir. Splitting and/or crushing of the tablet prior to administration, would be expected to compromise the required sustained release profile and therefore risk non-safe or non-efficacious dosing.
- The tablet film-coat also minimizes the potential formation of a photodegradant impurity which contains a beta-lactam ring (BMT-218946).[1] Splitting and/or crushing removes the protection provided by the film-coat and therefore there is an increased risk of forming the photodegradant to levels above the registered controls and a hypothetical risk of hypersensitivity reactions in individuals exposed to the impurity.
- If the tablet were to be broken or crushed prior to dosing, FTR could be lost in preparation preventing delivery of the full required dose.[1]

Some information contained in this response may not be included in the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling.

In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877–844–8872. Please consult the attached Prescribing Information.

This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

REFERENCES

1. Data on File. 2020N442160_00.
2. ViiV Healthcare. Global Data Sheet for fostemsavir, Version 04, July 1, 2022.