Fostemsavir (Rukobia, FTR)

Updated: March 31, 2026
Reviewed: March 31, 2026

Fostemsavir (FTR) is a prodrug of the active drug temsavir (TMR), a gp120-directed attachment inhibitor.

Summary

- Pharmacokinetic (PK) data are insufficient to make dosing recommendations for FTR during pregnancy.
- Clinical data are insufficient to characterize the risk for congenital anomalies associated with *in utero* exposure to FTR. No reproductive toxicity or teratogenicity concerns were identified in animal studies.

Human Studies in Pregnancy

Pharmacokinetics

No PK studies of FTR in pregnancy have been reported. A physiologically based PK model was developed to predict TMR PK in pregnant populations during each trimester to inform dosing. Simulations showed that TMR area under the curve in pregnant individuals decreased by 25% and 38% in the second and third trimesters, respectively. However, TMR exposure remained within the range observed in nonpregnant adults with no need for dose adjustment.[1]

Placental and Breast Milk Passage

No data are available on placental or breast milk passage of FTR in humans.

Teratogenicity/Adverse Pregnancy Outcomes

The Antiretroviral Pregnancy Registry (APR) provides updated birth defect data for FTR and other antiretroviral drugs twice a year through an interim report released in June and December. For the most recent data about FTR, refer to Table 5. Number of Birth Defects by Trimester of Earliest Exposure to Each Drug in the current APR interim report. Available data are limited and insufficient for drawing conclusions about the risk of birth defects among infants who were exposed to FTR.

Animal Studies

Carcinogenicity

Temsavir was not genotoxic or mutagenic *in vitro.*[2]

Reproduction/Fertility

FTR did not adversely affect the fertility of male or female rats at TMR exposures approximately 10 times (males) and 186 times (females) higher than those achieved in humans at the recommended dose.[2]

Teratogenicity/Adverse Pregnancy Outcomes

No adverse embryo-fetal effects were observed in rats and rabbits at TMR exposures of approximately 180 times (rats) and 30 times (rabbits) the exposure in humans at the recommended dose. Maternal toxicity and increased embryonic death were observed in rabbits at TMR exposures approximately 60 times those in humans. In a rat study conducted at drug exposures approximately 200 times those in humans, fetal abnormalities (cleft palate, open eyes, shortened snout, microstomia, misaligned mouth/jaw, and protruding tongue) and reductions in fetal body weights occurred in the presence of maternal toxicity.[2]

Placental and Breast Milk Passage

When FTR was administered to pregnant rats, FTR-related drug materials (e.g., TMR or metabolites) crossed the placenta and were detectable in fetal tissue. TMR is excreted in rat milk and was present at concentrations similar to those measured in maternal plasma on Day 11 postpartum.[2]

Excerpt From Table 14

Generic Name (Abbreviation) *Trade Name*	Formulation	Dosing Recommendations[a]	Use in Pregnancy
Fostemsavir (FTR) *Rukobia*	Extended-release tablet: 600 mg	**Pregnancy** *PK in Pregnancy* • No PK studies in human pregnancy *Dosing in Pregnancy* • Insufficient data to make dosing recommendation **Standard Adult Doses** *FTR (Rukobia)* • FTR 600 mg twice daily with or without food	No human data are available regarding placental passage. A study in rats demonstrates placental passage of TMR or other metabolites. Insufficient data to assess for teratogenicity in humans. No evidence of teratogenicity in rats or rabbits. **Note:** Please see FDA label for full list of drugs with potential interactions and drugs for which administration with FTR is contraindicated.

[a] Individual ARV drug doses may need to be adjusted in patients with renal or hepatic insufficiency (for details, see the Adult and Adolescent Antiretroviral Guidelines, Appendix B).

Key: ARV = antiretroviral; FTR = fostemsavir; PK = pharmacokinetic; TMR = temsavir

References

1. Salem F, Nguyen D, Bush M, et al. Development of a physiologically based pharmacokinetic model of fostemsavir and its pivotal application to support dosing in pregnancy. *CPT Pharmacometrics Syst Pharmacol*. 2024;13(11):1881-1892. Available at: https://pubmed.ncbi.nlm.nih.gov/38690782.

2. Fostemsavir (Rukobia) [package insert]. Food and Drug Administration. 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212950s004lbl.pdf.