

Ibalizumab-uiyk (Trogarzo, IBA)

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Animal Studies

Carcinogenicity

Carcinogenicity and mutagenicity studies of ibalizumab-uiyk (IBA) have not been conducted.¹

Reproduction/Fertility

Reproductive toxicology studies of IBA have not been conducted.¹

Teratogenicity/Adverse Pregnancy Outcomes

Early embryonic development and embryo-fetal development studies with IBA have not been conducted.

Placental and Breast Milk Passage

No data are available on placental or breast milk passage of IBA in animals.

Human Studies in Pregnancy

Pharmacokinetics

No pharmacokinetic studies of IBA in pregnant women have been reported.

Placental and Breast Milk Passage

No data are available on placental or breast milk passage of IBA in humans. However, because monoclonal antibodies are transported across the placenta during pregnancy, IBA has the potential to be transmitted from the mother to the developing fetus. Human immunoglobulin G also is present in human milk, although published data indicate that antibodies in breast milk do not enter the neonatal or infant circulation system in substantial amounts.¹

Teratogenicity/Adverse Pregnancy Outcomes

No data are currently available on the risk of birth defects in infants born to women who received IBA during pregnancy.

Excerpt from Table 8

Generic Name (Abbreviation) <i>Trade Name</i>	Formulation	Dosing Recommendations ^a	Use in Pregnancy
Ibalizumab-uiyk (IBA) <i>Trogarzo</i>	IBA (Trogarzo): <ul style="list-style-type: none"> Solution for IV infusion is available in single-dose vials 	Standard Adult Doses <ul style="list-style-type: none"> IBA 2,000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks Pregnancy <i>PKs in Pregnancy:</i> <ul style="list-style-type: none"> No PK studies in human pregnancy. <i>Dosing in Pregnancy:</i> <ul style="list-style-type: none"> Insufficient data to make dosing recommendations. 	No data available, but placental transfer of IBA, a monoclonal antibody, is possible. Insufficient data to assess for teratogenicity in humans.

^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, Table 10](#)).

Key: ARV = antiretroviral; IBA = ibalizumab; IV = intravenous; PK = pharmacokinetic

References

1. Ibalizumab (Trogarzo) [package insert]. Food and Drug Administration. 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761065s008lbl.pdf.