Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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**Ibalizumab (Trogarzo, IBA)**  
*(Last updated December 24, 2019, last reviewed December 24, 2019)*

**Animal studies**

*Carcinogenicity*

Carcinogenicity and mutagenicity studies of 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, since 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 is also 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*

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

Excerpt from Table 8

<table>
<thead>
<tr>
<th>Generic Name (Abbreviation)</th>
<th>Formulation</th>
<th>Dosing Recommendations</th>
<th>Use in Pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ibalizumab (IBA)</td>
<td>IBA (Trogarzo): • Solution for IV infusion is available in single-dose vials</td>
<td>Standard Adult Dose: • IBA 2,000-mg loading dose, followed by IBA 800-mg maintenance doses administered every 2 weeks</td>
<td>No data available, but placental transfer of IBA, a monoclonal antibody, is possible. Insufficient data to assess for teratogenicity in humans.</td>
</tr>
</tbody>
</table>

¹ 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**


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