Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

Downloaded from http://aidsinfo.nih.gov/guidelines on 2/21/2013 EST.

Visit the AIDS*info* website to access the most up-to-date guideline.

Register for e-mail notification of guideline updates at http://aidsinfo.nih.gov/e-news.

Downloaded from http://aidsinfo.nih.gov/guidelines on 2/21/2013 EST.

Rilpivirine (RPV, Edurant, TMC 278) (Last updated November 1, 2012; last reviewed November 1, 2012)

For additional information see Drugs@FDA: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

Formulations

Tablet: 25 mg

Combination Tablet:
- *With emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF):*
  RPV 25 mg + FTC 200 mg + TDF 300 mg (Complera)

Dosing Recommendations

Neonate/infant dose:
- Not approved for use in neonates/infants.

Pediatric dose:
- Not approved for use in children. A clinical trial in treatment-naive adolescents (aged 12–18 years) is under way.

Adolescent (>18 years of age)/adult dose (antiretroviral [ARV]-naive patients only):
- 25 mg once daily

Selected Adverse Events

- Depression, mood changes
- Insomnia
- Headache
- Rash

Special Instructions

- Instruct patients to take rilpivirine with a meal of at least 500 calories (a protein drink alone does not constitute a meal).
- Do not use rilpivirine with other non-nucleoside reverse transcriptase inhibitors.
- Do not use rilpivirine with proton pump inhibitors.
- Use rilpivirine with caution when co-administered with a drug with a known risk of torsade de pointes (http://www.qtdrugs.org/).
- Use rilpivirine with caution in patients with HIV RNA >100,000 copies/mL because of increased risk of virologic failure.

Metabolism

- Cytochrome P450 (CYP) 3A substrate
- Dosing in patients with hepatic impairment: No dose adjustment is necessary in patients with mild or moderate hepatic impairment.
- Dosing in patients with renal impairment: No dose adjustment is required in patients with mild or moderate renal impairment.
- Use rilpivirine with caution in patients with severe renal impairment or end-stage renal disease. Increase monitoring for adverse effects because rilpivirine concentrations may be increased in patients with severe renal impairment or end-stage renal disease.

Downloaded from http://aidsinfo.nih.gov/guidelines on 2/21/2013 EST.

Drug Interactions:

- *Metabolism:* Rilpivirine is a CYP 3A substrate and requires dosage adjustments when administered with CYP 3A-modulating medications.
- Before rilpivirine is administered, a patient's medication profile should be carefully reviewed for potential drug interactions.

Major Toxicities:

- *More common:* Insomnia, headache, and rash.
- *Less common (more severe):* Depression or mood changes.

Resistance: The International AIDS Society-USA (IAS-USA) maintains a list of updated resistance mutations (see http://www.iasusa.org/resistance_mutations/index.html).

Pediatric Use: The pharmacokinetics, safety, and efficacy of rilpivirine in pediatric patients have not been established. An international trial currently under way is investigating a 25-mg dose of rilpivirine in combination with two nucleoside reverse transcriptase inhibitors in antiretroviral-naive children aged 12 to 18 years who weigh at least 40 kg.

Downloaded from http://aidsinfo.nih.gov/guidelines on 2/21/2013 EST.