Isentress® (raltegravir) – Expanded indication

- On November 22, 2017, the FDA approved Merck's Isentress (raltegravir) in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients weighing ≥ 2 kg.
    - Previously, in the pediatric population, Isentress was indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in pediatric patients 4 weeks of age and older.
    - Isentress is not recommended in pre-term neonates or in pediatric patients weighing < 2 kg.
- Isentress is also indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients.
    - Raltegravir is also available as Isentress® HD. Isentress HD is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients, and in pediatric patients weighing ≥ 40 kg.
- The safety and pharmacokinetics of Isentress for oral suspension were evaluated in 42 full-term HIV-1 exposed neonates at high risk of acquiring HIV-1 infection. HIV-1 status was assessed at birth, week 6, and week 24. All patients were HIV-1 negative at completion of the study.
- The safety profile of Isentress in full-term HIV-1 exposed neonates was comparable to that observed in adults.
- In pediatric patients from birth to 4 weeks of age weighing ≥ 2 kg, the recommended dosage of Isentress oral suspension is based on body weight and given once or twice daily.

Body weight (kg)	Volume (dose) of oral suspension
Birth to 1 week old – once daily dosing*	
2 kg to < 3 kg	0.4 mL (4 mg) once daily
3 kg to < 4 kg	0.5 mL (5 mg) once daily
4 kg to < 5 kg	0.7 mL (7 mg) once daily
1 week to 4 weeks old – twice daily dosing†	
2 kg to < 3 kg	0.8 mL (8 mg) twice daily
3 kg to < 4 kg	1 mL (10 mg) twice daily
4 kg to < 5 kg	1.5 mL (15 mg) twice daily

* Dosing recommendations are based on approximately 1.5 mg/kg/dose
† Dosing recommendations are based on approximately 3 mg/kg/dose

- For the recommended dosage of Isentress in other patient populations, including adults and pediatric patients ≥ 4 weeks of age, please refer to the drug label.