

Isentress[®] HD (raltegravir) – New formulation approval

- On May 30, 2017, [Merck announced](#) the FDA approval of [Isentress HD \(raltegravir\)](#) once daily film-coated tablets, in combination with other antiretroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in adult patients, and pediatric patients weighing at least 40 kg, who are treatment-naïve or virologically suppressed on an initial regimen of Isentress 400 mg twice daily.
- Isentress is also available as 25 mg and 100 mg chewable tablets, 400 mg film-coated tablets, and a 100 mg oral suspension for twice daily dosing.
- The approval of Isentress HD is supported by an active-controlled study involving 797 HIV-1 subjects. Isentress HD was compared to Isentress 400 mg twice daily in combination with other antiretroviral agents.
 - At week 48, 89% of subjects treated with Isentress HD achieved viral suppression vs. 88% receiving Isentress 400 mg twice daily (treatment difference = 0.5% [95% CI: -4.2%, 5.2%])
 - The result was consistent across demographic groups at initiation of therapy and a variety of patient populations, including those with high viral load.
- Warnings and precautions for raltegravir include severe skin and hypersensitivity reactions, immune reconstitution syndrome, and phenylketonurics.
- The most common adverse events of moderate to severe intensity ($\geq 2\%$) with raltegravir use were insomnia, headache, dizziness, nausea and fatigue.
- Creatine kinase elevations were observed in subjects who received Isentress or Isentress HD. Myopathy and rhabdomyolysis have been reported. Use with caution in patients at increased risk of myopathy or rhabdomyolysis, such as patients receiving concomitant medications known to cause these conditions and patients with a history of rhabdomyolysis, myopathy or increased serum creatine kinase.
- In adults and pediatric patients weighing ≥ 40 kg who are either treatment-naïve or virologically suppressed on an initial regimen of Isentress 400 mg twice daily, the recommended dose of Isentress HD is 1200 mg (2 x 600 mg tablets) orally once daily.
 - Because the formulations have different pharmacokinetic profiles, do not substitute Isentress chewable tablets or oral suspension for Isentress 400 mg film-coated tablets or Isentress HD.
 - Isentress film-coated tablets must be swallowed whole.
 - Consult the drug label for specific dosing guidance for the chewable tablets, oral suspension, or 400 mg film-coated tablets.
- The price of Isentress HD will be the same as Isentress twice daily.
- Merck plans to launch Isentress HD in approximately 4 weeks. Isentress HD will be available as 600 mg film-coated tablets.