



Selzentry® (maraviroc) – Expanded Indication, New Formulation

- On November 4, 2016, the [FDA announced](#) Viiv Healthcare's [Selzentry \(maraviroc\)](#) 20 mg/mL oral solution and 25 mg and 75 mg tablets in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in patients 2 years of age and older weighing at least 10 kg.
 - Previously, Selzentry was approved for use in adults.
 - Selzentry is currently available as 150 mg and 300 mg tablets.
 - Selzentry is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.
- The expanded indication of Selzentry was based on a clinical study of 103 treatment-experienced, CCR5-tropic, HIV-1-infected pediatric patients aged 2 to less than 18 years weighing at least 10 kg.
 - At 48 weeks, 48% of patients treated with Selzentry and optimized background therapy achieved plasma HIV-1 RNA < 48 copies/mL and 65% of patients achieved plasma HIV-1 RNA < 400 copies/mL. The mean CD4+ cell count increase was 247 cells/mm³.
- Selzentry carries a boxed warning regarding hepatotoxicity.
- The most common adverse reactions in treatment-experienced pediatric patients (≥ 3%) were vomiting, abdominal pain, diarrhea, nausea, and dizziness.
- Prior to initiation of Selzentry, patients should be tested for CCR5 tropism using a highly sensitive tropism assay. Outgrowth of pre-existing low-level CXCR4- or dual/mixed-tropic HIV-1 not detected by tropism testing at screening has been associated with virologic failure on Selzentry.
- Refer to the drug label for specific liver tests that should be monitored prior to Selzentry initiation and during therapy.
- The recommended dose of Selzentry in pediatric patients ranges from 50 mg to 300 mg twice daily. The dose should be based on body weight and differs based on concomitant medications due to drug interactions.
 - The oral solution formulation should be prescribed to children who are unable to swallow the tablets.
 - Selzentry tablets and oral solution may be taken without regard to food.
 - Consult the drug label for recommended doses of Selzentry for adults.
- Viiv Healthcare plans to launch the new formulations of Selzentry in mid-January 2017.



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