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# ***Urgent HIV Treatment Alert***

*This message is intended to apprise you of important HIV/AIDS-related information, and developments in HIV Treatment and medications.*

## **FDA approves Selzentry (maraviroc) 150 mg and 300 mg tablets, a CCR5 co-receptor antagonist used in combination with other antiretroviral products for the treatment of adults infected with CCR5-tropic HIV-1.**

On August 6, 2007, the Food and Drug Administration (FDA) approved Selzentry (maraviroc) 150 mg and 300 mg tablets, a CCR5 co-receptor antagonist used in combination with other antiretroviral products for the treatment of adults infected with CCR5-tropic HIV-1.

Maraviroc received a priority review by the FDA and is the first drug approved in the new class of anti-HIV medications called CCR-5 co-receptor antagonist.

Rather than fighting HIV inside white blood cells, like most antiretrovirals used to treat infection with HIV, maraviroc prevents the virus from entering uninfected cells by blocking the predominant route of entry, the CCR5 co-receptor, a protein on the surface of immune cells affected by HIV. Among patients who have previously received HIV medications, approximately 50 percent to 60 percent have circulating CCR5-tropic HIV.

Maraviroc, in combination with other antiretroviral agents, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable virus, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

The approval of maraviroc is based on analyses of plasma HIV-1 RNA levels in two controlled studies each of 24 weeks duration with over 1000 clinical trial participants of which 840 received maraviroc. Both studies were conducted in clinically advanced, 3-class antiretroviral (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitor, protease inhibitors or fusion inhibitor, specifically enfuvirtide) treatment-experienced adults with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

The following points should be considered when initiating therapy with maraviroc :

- Tropism testing and treatment history should guide the use of maraviroc .
- Use of maraviroc is not recommended in patients with dual/mixed or CXCR4-tropic HIV-1 as efficacy was not demonstrated in a phase 2 study of this patient group.
- The safety and efficacy of maraviroc have not been established in treatment-naïve adult patients or pediatric patients.

The recommended dose of maraviroc differs based on concomitant medications due to drug interactions (See attached pdf label, Section 2, Dosage and Administration). Maraviroc can be taken with or without food.

The product label includes a boxed warning about liver toxicity (hepatotoxicity) and a statement in the Warnings/Precautions section about the possibility of increased risk for cardiovascular events such as heart attack or symptomatic postural hypotension (dizziness upon quickly standing). The most common adverse events reported with maraviroc were cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness.

Maraviroc has not been tested or studied in pregnant women. The FDA recommends HIV positive women should not breast feed, whether or not they are on antiretroviral medications.

Maraviroc is distributed by Pfizer Inc., of New York and is available as 150 mg or 300 mg tablets.



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