

MARAVIROC (MVC)

GENERAL INFORMATION

- Therapeutic class: Chemokine co-receptor 5 (CCR5) antagonist (entry inhibitor).
- WHO guidelines: Not currently included in WHO guidelines. Indicated for treatment-experienced adult patients infected with only CCR5 tropic HIV-1 detectable strains, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.¹⁹⁶
- Originator company and product brand name: Pfizer, Selzentry (US) and Celsentri (Europe). In April 2009, Pfizer and GlaxoSmithKline jointly announced the creation of ViiV, a new joint venture focusing solely on the R&D and commercialisation of HIV medicines.
- First approval by U.S. Food and Drug Administration (FDA): August 2007.²³
- WHO Model List of Essential Medicines (EML): Not included in the 17th edition.²⁴
- World sales of originator product: There are no sales figures listed in the company's annual report.
- Patents: The basic patent was applied for by Pfizer in December 1999¹⁹⁷ and is due to expire in 2019. Pfizer also owns an additional patent more specifically related to crystalline maraviroc,¹⁹⁸ which may run up to 2021.

PRICE INFORMATION

Developing country prices in US\$ per patient per year, as quoted by companies.

The price in brackets corresponds to the price of one tablet.

	Daily dose	ViiV
Who can access this price?		See annex 2
MVC 150mg tablet	4*	1584 (1.085)

*The dose is dependent on concurrent administered medications.

SPOTLIGHT ON ACCESS ISSUES

Maraviroc (MVC) is classed as a CCR5 co-receptor antagonist that targets the penetration of cells by the HIV virus. This drug option is predominately used in the developed world as 'salvage therapy' for patients who are already resistant to multiple drug classes. Not all patients will benefit from this drug, as only some HIV viruses use this CCR5 co-receptor.

The recommendation is for patients to have a tropism test to look for this co-receptor prior to treatment. In developing countries, where basic laboratory monitoring is not always available, the reality of this type of testing being available is limited. Today, this test is not widely available and is expensive, costing approximately \$1,900.¹⁹⁹

In 2011, ViiV clarified their pricing structure (see annex 2), confirming

that their standardised price discounts were not in fact available to all fully-financed Global Fund or PEPFAR programmes, contrary to previous announcements. Global Fund financed programmes in middle-income countries have not been and will not be eligible for those prices, and will have to negotiate prices on a case-by-case basis.

Patents

Pfizer obtained a patent in India in 2007.²⁰⁰ This patent blocks the manufacture of generic formulations of MVC in India, limiting the much-needed competition that historically has been shown to lead to price reductions.

An Indian pharmaceutical company, Natco Pharmaceuticals reportedly sent a notice for a voluntary licence to Pfizer in November 2010 seeking to manufacture and sell its generic

MVC at about one-fifth the price.²⁰¹ If negotiations with Pfizer fail, Natco can seek a compulsory licence under the terms of the Indian patent law.

Pfizer has applied for product patents and patents for the crystal form in Brazil, South Africa, India, China, ARIPO²⁰² and OAPI countries.²⁰³ To date, patents on the crystal form have been granted in India,^{204, 205} China, and in ARIPO and OAPI countries.

Paediatrics

The safety and efficacy of MVC in patients under 16 years of age have not been established.

As few treatment options exist for children with HIV, it is critical that paediatric studies of MVC be completed and adapted formulations be made available.