

FOSAMPRENAVIR (FPV or f-APV)

GENERAL INFORMATION

- Therapeutic class: Protease inhibitor (PI).
- WHO guidelines: Not currently included in WHO guidelines.
- Originator company and product brand name: GlaxoSmithKline (GSK) and Vertex Pharmaceuticals, Lexiva. In April 2009, Pfizer and GSK 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): October 2003.²³
- 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 companies' annual report.
- Patents: The basic patent was applied for by Vertex Pharmaceuticals in March 1998,¹⁵⁶ and due to expire in 2018. Fosamprenavir, a phosphate ester prodrug of amprenavir,¹⁵⁷ was developed and launched by GSK, under licence from Vertex. GSK also holds patents related to a crystalline form of the calcium salt of FPV,¹⁵⁸ due to expire in 2019.

PRICE INFORMATION

	Daily dose	ViiV
Who can access this price?		See annex 2
FPV 50mg/ml oral suspension	12ml*	837 (0.191/ml)
FPV 700mg tablet	2*	1131 (1.549)

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

The price in brackets corresponds to the price of one tablet/ml of oral suspension.

*The dose of FPV must be boosted with RTV 100mg twice a day.

SPOTLIGHT ON ACCESS ISSUES

In 2010, WHO recommendations for second-line therapy included two 'preferred' protease inhibitors (PI), to be taken in combination with two NRTIs. They are atazanavir (ATV) boosted with ritonavir (RTV) and lopinavir/ritonavir (LPV/r).⁷ As fosamprenavir (FPV) was not identified as one of the priority products, its use will be limited in the developing world.⁷

While FPV/r based regimens show good antiviral efficacy and are generally well tolerated in treatment-naïve patients, the experience of this drug in developed countries is limited and little comparative data is available in treatment-experienced patients.¹⁵⁹

FPV, like all PIs (with the exception of nelfinavir (NFV)), requires boosting with ritonavir (RTV). Abbott's heat-stable ritonavir received marketing approval in the U.S. and Europe in early 2010. Registering this new

formulation in developing countries will be crucial in order to allow the use of other PIs than lopinavir. A generic heat-stable RTV is now available and was WHO prequalified in late 2010.

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

Patent applications have been filed in many developing countries.

In Brazil, the basic patent was rejected by the patent office, although in December 2009 ViiV filed an appeal

against the decision.

In China, South Africa, ARIPO and OAPI countries,¹⁶⁰ most patents have been granted.

In June 2010, India granted a patent to Vertex Pharmaceuticals that covers fosamprenavir salts, including calcium which is the marketed salt.³²³

There are no generic formulations of this product available today.

Paediatrics

FPV was approved for use in children above the age of two in October 2007.²³

A paediatric suspension is available. However, FPV must be given with a RTV booster, but the RTV solution currently available has a bitter aftertaste and contains 43% alcohol, and is thus not adapted for children, limiting the use of FPV in this population.

