

INDINAVIR (IDV)

GENERAL INFORMATION

- Therapeutic class: Protease inhibitor (PI).
- WHO guidelines: Not currently included in WHO guidelines.
- Originator company and product brand name: Merck, Crixivan.
- First approval by U.S. Food and Drug Administration (FDA): March 1996.²³
- WHO Model List of Essential Medicines (EML): 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 filed by Merck in 1992 and is due to expire in 2012 in countries granting 20-year patents.¹⁶¹

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 capsule. Products quality-assured by US FDA or WHO prequalification (as of May 2011) are in **bold**.

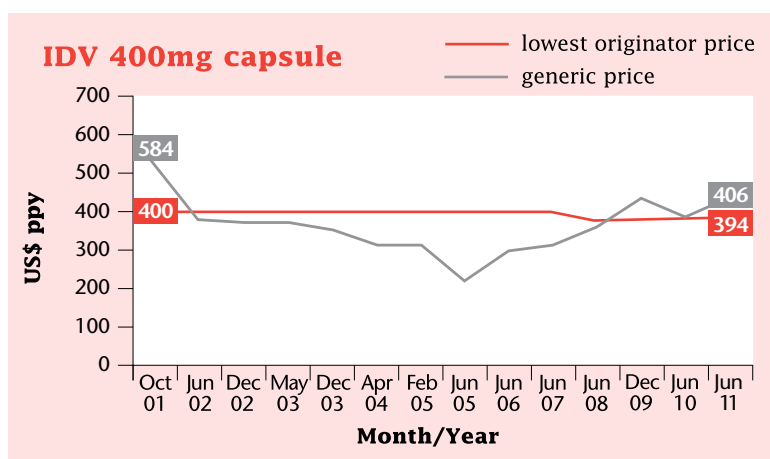
	Daily dose	Merck	Aurobindo	Cipla	Hetero
Who can access this price?		See annex 2 & annex 10**		See annex 2	
IDV 400mg capsule	4*	394 (0.270)	292 (0.200)	422 (0.289)	406 (0.278)

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

**For the first time this year, Merck has decided not to give standardised price discounts to Category 2 countries. See 'Spotlight on access issues' below.

Evolution of the lowest price quoted for developing countries since 2001:

As of May 2011, two generic sources of IDV 400mg capsule were quality-assured by US FDA or WHO prequalification. Only one of these sources provided prices for this document, and is the one shown here.



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). As IDV was not identified as one of the priority products, its use will be limited in the developing world.⁷

IDV, like all PIs (with the exception of nelfinavir (NFV)), requires boosting with 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.

Some generic manufacturers have stopped production of IDV, or only manufacture it for specific orders, because of a decrease in demand for this product.

In 2011, Merck ceased offering standardised price discounts to all lower middle- and upper middle-income countries according to the World Bank Classification (see annex 6 for a list of these countries).

The company proposes instead to negotiate discounted prices on a case-by case basis, based on country income and disease burden.

Patents

In Brazil, indinavir is one of the ARVs produced locally. The patent application was filed in 1994, at a time when the country did not grant patents on pharmaceuticals, and was therefore rejected.

Paediatrics

The optimal dosing regimen for the use of IDV in paediatric patients has not been established.¹⁶²

No paediatric formulation exists.