

ZIDOVUDINE/LAMIVUDINE/ ABACAVIR (AZT/3TC/ABC)

GENERAL INFORMATION

- Therapeutic class: Three NRTI in a triple fixed-dose combination.
- WHO guidelines: Indicated under specific conditions in adults, adolescents and children.^{6,22}
- Originator company and product brand name: GlaxoSmithKline (GSK), Trizivir. 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): November 2000.²³
- WHO Model List of Essential Medicines (EML): Individual medicines included in 17th edition. The WHO Expert Committee on the Selection and Use of Essential Medicines recommends and endorses the use of fixed-dose combinations and the development of appropriate new fixed-dose combinations.²⁴
- World sales of originator product: 2010: US\$ 233 million; 2009: \$307 million; 2008: \$350 million; 2007: \$455 million; 2006: \$529 million; 2005: \$598 million; 2004: \$635 million.^{163, 25, 26, 27, 28, 29, 30}
- Patents: Most patents on zidovudine (AZT), lamivudine (3TC), AZT/3TC or abacavir (ABC) also affect this combination. In addition, GSK applied for patents more specifically related to the triple combination.³⁰⁸

PRICE INFORMATION

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

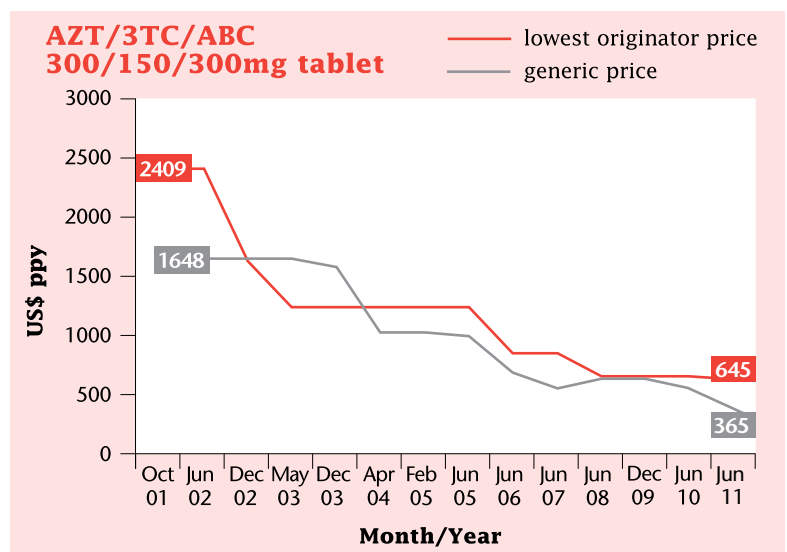
The price in brackets corresponds to the price of one tablet. Products quality-assured by US FDA or WHO prequalification (as of May 2011) are in **bold**.

	Daily dose	ViiV	Matrix	Ranbaxy
Who can access this price?		See annex 2		
AZT/3TC/ABC 60/30/60 mg tablet	4		244 (0.167)	
AZT/3TC/ABC 300/150/300 mg tablet	2	645 (0.884)	365 (0.500)	548 (0.750)

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

As of May 2011, two generic source of AZT/3TC/ABC 300/150/300mg tablet were quality-assured by US FDA or WHO prequalification. The one with the lowest price is shown here.

Since 2002, the originator price has decreased by 73%, while generic prices have dropped by 78%.



SPOTLIGHT ON ACCESS ISSUES

This FDC is the only triple NRTI formulation available, and is no longer a preferred regimen in the developed world,³²⁰ where its use is limited to individuals with contra-indication to NNRTI-based regimens or who are unable to tolerate them. This applies particularly to people co-infected with TB/HIV, pregnant women, patients with chronic viral hepatitis and those with HIV-2 infection.²²

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

GSK could not apply for basic patents related to ABC, AZT or 3TC in some developing countries such as India, which did not grant patents on pharmaceuticals at the time. This allowed Indian generic companies to develop generic versions of each medicine, and of the combination.

However, GSK widely applied for patents in other developing countries, where possible.

In India, GSK had applied for patents more specifically related to the fixed-dose combination. The company withdrew the patent application after a pre-grant opposition was filed by civil society in 2006.³²¹

Paediatrics

In its 2010 guidelines for antiretroviral therapy for HIV in infants and children, WHO recommends AZT/3TC/ABC as an option for TB/HIV co-infected patients.²² This is crucial for a small cohort of patients below three years of age, for whom dosing studies for EFV do not exist.

A generic paediatric formulation of AZT/3TC/ABC has been developed and quality-assured by WHO prequalification. However, this product is not commercially available yet because of insufficient demand.