



LAMIVUDINE (3TC)

GENERAL INFORMATION

- Therapeutic class: Nucleoside reverse transcriptase inhibitor (NRTI).
- WHO guidelines: Indicated for first- and second-line for adults, adolescents and children.^{6,22}
- Originator company and product brand name: GlaxoSmithKline (GSK), Epivir. 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 1995.²³
- WHO Model List of Essential Medicines (EML): Included in the 17th edition.²⁴
- World sales of originator product: 2010: US\$ 186 million; 2009: \$197 million; 2008: \$225 million; 2007: \$309 million; 2006: \$398 million; 2005: \$398 million; 2004: \$549 million.^{163, 25, 28, 29, 30}
- Patents: The basic patent on emtricitabine (FTC) and 3TC was filed by IAF Biochem in 1990 and should therefore have expired in 2010 in countries with 20-year patent terms. As the molecular structure of FTC and 3TC are very closely related, the same patent covers both these drugs.¹³³ GSK obtained a licence from IAF to manufacture 3TC and filed additional patents on new forms of 3TC in 1992, which are due to expire in June 2012.¹⁶⁴ GSK also applied for a new formulation patent in 1998. This patent was granted in Brazil, China and in ARIPO countries.¹⁶⁵

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

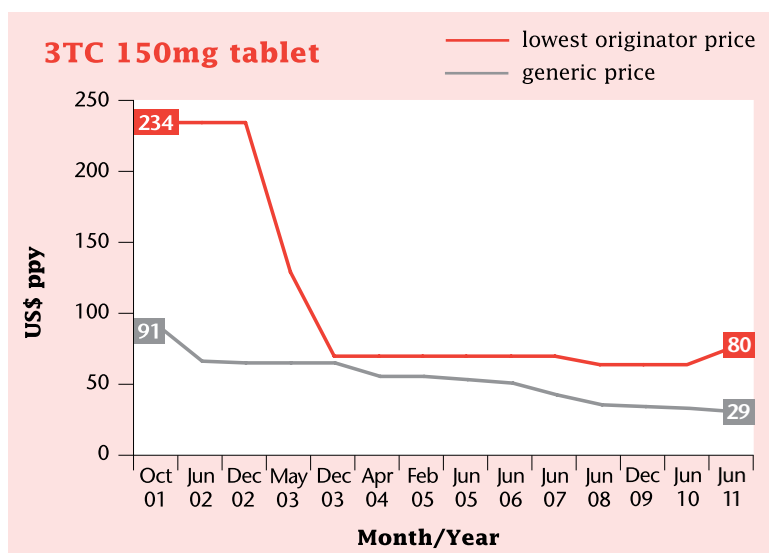
	Daily dose	ViiV	Alkem	Aspen	Aurobindo (CF)	Cipla (CF)	Hetero (CF)	Matrix (CF)	Micro Labs	Ranbaxy	Strides
Who can access this price?		See annex 2									
3TC 10mg/ml oral solution	10ml	212 (0.058/ml)		33 (0.009/ml)	29 (0.008/ml)	55 (0.015/ml)	37 (0.010/ml)				
3TC 150mg tablet	2	80 (0.109)	42 (0.058)	29 (0.040)	34 (0.047)	33 (0.045)	33 (0.045)	31 (0.042)	31 (0.042)	34 (0.047)	29 (0.040)
3TC 300mg tablet	1				24 (0.067)	41 (0.113)	38 (0.103)		26 (0.071)		

(CF) The Clinton Foundation has negotiated with this manufacturer for reduced prices on some formulations for countries in their consortium. See annex 13 for details.

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

As of May 2011, nine generic sources of 3TC 150mg tablet were quality-assured by US FDA or WHO prequalification. The one with the lowest price is shown here.

Since 2001, the originator price has decreased by 66%, while generic prices have dropped by 68%.



SPOTLIGHT ON ACCESS ISSUES

Lamivudine (3TC) is a widely-used ARV both in first- and second-line regimens. It has been an important component of fixed-dose combinations that have fostered treatment scale-up in resource-limited settings.

According to the WHO treatment guidelines, “FTC is an equivalent alternative to lamivudine (3TC) as it is structurally related to 3TC, shares the same efficacy against HIV and hepatitis B virus (HBV) and has the same resistance profile.”⁶

The latest WHO 2010 guidelines also recommend using TDF with either FTC- or 3TC-containing antiretroviral regimens in all HIV/HBV co-infected individuals needing treatment.⁷

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.

In February 2011, Shionogi-ViiV Healthcare announced³⁶ the start of a phase III trial for a new fixed-dose combination including ABC, lamivudine (3TC) and a new integrase inhibitor S/GSK1349572 (an investigational drug known as dolutegravir, now in phase III clinical development).³⁷

Patents

Generic competition for 3TC originated in countries with manufacturing capacity where the drug is not under patent, such as India, Thailand and Brazil.

Paediatrics

3TC is approved for use and is widely used in children. In its 2010 guidelines for antiretroviral therapy for HIV in infants and children, WHO recommends 3TC to be given with either ABC, d4T or AZT and either an NNRTI or a PI in the first-line. 3TC can also be part of second-line regimens, depending on what has been used as a first-line. 3TC is part of both of the most commonly used first-line regimens for children today (3TC/d4T/NVP and AZT/3TC/NVP).

Today, once-daily dosing of 3TC is only recommended for patients over 16; more studies are needed to confirm the safety of daily dosing of 3TC in children.⁴³

An oral solution of 3TC is available. As of May 2011, two generic sources were quality-assured by either US FDA or WHO prequalification.

Generic manufacturers have been developing both double and triple fixed-dose combinations containing 3TC. As of May 2011, ten sources of paediatric triple FDCs containing 3TC were quality-assured by either US FDA or WHO prequalification. All are produced by generic companies.