

# EMTRICITABINE (FTC)

## GENERAL INFORMATION

- Therapeutic class: Nucleoside reverse transcriptase inhibitor (NRTI).
- WHO guidelines: Indicated for first- and second-line for adults.<sup>6</sup>
- Originator company and product brand name: Gilead, Emtriva.
- First approval by U.S. Food and Drug Administration (FDA): July 2003.<sup>23</sup>
- WHO Model List of Essential Medicines (EML): Included in the 17th edition.<sup>24</sup>
- World sales of originator product: 2010: US\$ 28 million; 2009: \$28 million; 2008: \$31 million; 2007: \$32 million; 2006: \$36 million; 2005: \$47 million; 2004: \$58 million.<sup>128, 129, 130, 131, 132</sup>
- Patents: The basic patent on FTC and lamivudine (3TC) was filed by IAF Biochem in 1990 and is due to expire in 2010. As the molecular structure of FTC and 3TC are very closely related, the same patent covers both these drugs.<sup>133, 134</sup>

Emory University also applied for a series of patents that relate to FTC between 1990 and 1992.<sup>135, 136</sup> These are due to expire between 2010 and 2012. In 2005, Gilead acquired the royalty interest for FTC under a \$525 million agreement with Emory University.<sup>137</sup>

## 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	Aurobindo	Cipla
Who can access this price?		See annex 2	
FTC 200mg capsule	1	<b>61</b> <b>(0.167)</b>	<b>97</b> <b>(0.267)</b>

## SPOTLIGHT ON ACCESS ISSUES

Emtricitabine (FTC) is not offered as part of Gilead's Access Program and is neither registered nor marketed in developing countries. It is, however, available in co-formulation with tenofovir (TDF) and efavirenz (EFV). It is a widely-used ARV both in first- and second-line regimens.

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."<sup>6</sup>

FTC or 3TC are also recommended for second-line treatment, to be used with either zidovudine (AZT) or tenofovir (TDF), to which a boosted protease inhibitor (PI) should be added.

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

### Patents

Although basic patents on FTC could not be applied for in India because the country did not grant patents on pharmaceuticals at the time, Gilead reported holding patent rights on FTC in 45 other developing countries.<sup>138</sup>

In mid-2006, Gilead signed licensing agreements with generic manufacturers in India, allowing them to manufacture and export generic versions of Gilead's TDF in combination with other ARVs – including FTC – to a limited list of countries, in return for the payment of a 5% royalty.<sup>139</sup>

### Paediatrics

FTC is approved for use in children from three months through to 17 years and has the advantage of once-daily dosing.<sup>140</sup>

Paediatric formulations are available. The solution produced by Gilead is not adapted to developing world needs, however, as it requires refrigeration prior to dispensing and must be used within three months of opening and stored at temperatures below 25°C.

In addition, Gilead offers no reduced pricing for the developing world.

To simplify treatment for all children, there is an urgent need for child-adapted formulations of FTC to be made available, and generic paediatric FTC formulations to be quality-assured by WHO prequalification.