

ABC/3TC (120/60 mg) Tablet Informational Brief

This informational brief provides antiretroviral therapy (ART) program managers, implementing partners, clinicians, procurement and supply chain managers, and other relevant stakeholders with key points to consider regarding the introduction of the new, scored, fixed dose combination (FDC) tablet containing 120mg of abacavir (ABC) and 60mg of lamivudine (3TC) tablets. The information contained herein does not replace that provided in the product insert, as approved by the regulatory authority. Practitioners are encouraged to read the approved product package insert and current normative treatment guidelines for more detailed and up-to-date information regarding prescribing of ABC and 3TC.

ABC/3TC (120/60 mg) Product Information	
Presentation	Dispersible, Scored
Manufacturer	Mylan
SRA Approval	US FDA (tentative), October 2014
IATT Status	Optimal ¹
Pack Size	30 tablets per HPDE bottle
Price	Price parity across weight bands to ABC/3TC (60/30 mg) dispersible, scored*
Dosing	Once or twice daily dosing across all WHO weight bands as recommended

*2015 CHAI reference price of USD 3.50 per pack

Key Benefits

Based on recommended dosing by weight band, the use of ABC/3TC (120/60 mg) can **significantly decrease pill burden** in children by at least 50% compared to existing formulations of ABC, particularly when used as a once daily regimen. The reduced pill burden **may improve patient adherence** and **simplify the supply chain** at **no additional cost** to national HIV programs.

Furthermore, ABC/3TC (120/60 mg) may prevent sub-optimal dosing that occurs with use of adult formulations and can lead ease administration as pill cutting may be avoided. A dosing chart is included in the table below for quantification of ABC/3TC formulation requirements by weight band.

Simplified Weight Band Daily Dosing Schedule for ABC/3TC Formulations (# of tablets of relevant formulation)			
Weight Band (Kg)	ABC/3TC (60/30 mg)	ABC/3TC (120/60 mg)	ABC/3TC (600/300 mg)
3-5.9	2	1	N/R
6-9.9	3	1.5	N/R
10-13.9	4	2	N/R
14-19.9	5	2.5	N/R
20-24.9	6	3	N/R
25-34.9	1 adult tab (600/300mg)	1 adult tab (600/300mg)	1

Countries are encouraged to place orders for this product in line with quarterly order dates advised by the ARV procurement Working Group (APWG) to reduce the risk of sub-optimal batches and potentially longer lead times.

Recommended Dates to Place Orders with Suppliers	
Q2 2016	1 July 2016
Q3 2016	30 September 2016
Q4 2016	20 December 2016
Q1 2017	31 March 2017
Q2 2017	30 June 2017

¹ Inter-Agency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children (IATT). "Update to the optimal list of paediatric ARV formulations." March 2015. <http://www.emtct-iatt.org/wp-content/uploads/2015/05/Updated-Formulary-04012015.pdf>

