



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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Reference: 2021/05/07/CMU/01

NOTICE: AVAILABILITY OF ABACAVIR 120MG, LAMIVUDINE 60MG DISPERSIBLE, SCORED TABLETS FOR PAEDIATRIC PATIENTS

The Paediatric Hospital Level Standard Treatment Guidelines (STGs), the Essential Medicines List (EML) and the South African National Department of Health 2019 Antiretroviral Therapy Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates recommend the use of Abacavir (ABC) and Lamivudine (3TC) as part of the antiretroviral regimens in the weight bands 3-24.9kg (\geq 4 weeks of age to <10 years of age).

Recently, the combination formulation ABC/3TC 120/60mg dispersible, scored tablets have been registered with the South African Health Products Regulatory Authority providing an alternative fixed dose combination treatment for patients on ABC (60 mg) dispersible tablet, ABC (20 mg/ml) oral solution, 3TC (50/5 mg/ml) oral solution, and 3TC (50/5 mg/ml) oral solution. See Table 1 below for dose recommendations according to weight.

Table 1: Dosing of Abacavir 120mg, Lamivudine 60mg dispersible, scored tablets by weight

Abacavir (ABC) + Lamivudine (3TC) 120/60mg Dispersible Scored Tablets	
Target dose	Same as for individual medicines ONCE daily
<i>Weight</i>	
3-4.9	1 tablet once daily
5-5.9	
6-9.9	1.5 tablets once daily
10-13.9	2 tablets once daily
14-19.9	2.5 tablets once daily
20-24.9	3 tablets once daily
25-29.9	1 x 600/300 mg tablet once daily
30-34.9	
\geq40	

Procurement of Abacavir 120mg, Lamivudine 60mg dispersible, scored tablets

Utilisation of ABC/3TC 120/60mg will simplify daily dosing for paediatric patients, which has been shown to be beneficial to patient adherence on antiretrovirals (ARVs), whilst also being available at a lower price than for the single agents, see Annexure 1 for further details.

Quotations have been supplied for provinces to procure these items (see Table 2 below, and Annexure 2 for Provincial Procurement Quotation). Provinces can procure these items as a buy-out at their discretion.

Table 2: Product summary for Abacavir 120mg, Lamivudine 60mg dispersible, scored tablets:

Product description	Cost per pack (per quotation)	Quantity (packs) & Lead Times	NSN
Abacavir/Lamivudine 120mg/60mg dispersible scored; 60 tablets	R120.10 (Cipla)	17 500 – 7 days	222001211
	R120.10 (Mylan)	17 500 – 56 days	

For further assistance on how and when to use this formulation please contact:

National HIV & TB Care Worker Hotline: 0800 212 506 or 021 406 6782

National HIV & TB Care Worker Hotline: 071 840 1572

- This helpline can be contacted *via* SMS/Please call me/WhatsApp

Right to Care Paediatric and Adolescent HIV Helpline 082 352 6642

Right to Care Adult HIV Helpline 082 957 6698

- These helplines can be contacted via call/SMS/Please call me/WhatsApp

KZN Paediatric Hotline 0800 006 603

Provinces and Healthcare facilities are requested to distribute and communicate this information in consultation with their Pharmaceutical and Therapeutics Committees. Kindly share with all healthcare professionals and relevant stakeholders.

Comments may be submitted *via* e-mail:

Stock queries:

Ms Babalwa Melitafa

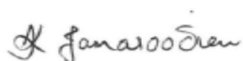
E-mail: Babalwa.Melitafa@health.gov.za

Clinical queries:

Essential Drugs Programme

E-mail: SAEDP@health.gov.za

Kind regards



MS K JAMALOODIEN
DIRECTOR: AFFORDABLE MEDICINES
DATE: 18 May 2021

ANNEXURE 1: COST AND DAILY DOSING CONSIDERATIONS OF USING ABACAVIR 120MG, LAMIVUDINE 60MG DISPERSIBLE, SCORED TABLETS

Utilisation of ABC/3TC 120/60mg will simplify daily dosing on paediatric patients, which has been shown to be beneficial to patient adherence on antiretrovirals (ARVs). Details of this can be seen in table 3.

Table 3: Simplified Daily Dosing*

Product	3-5.9kg	6-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg	
ABC/3TC (120/60 mg) Dispersible, Scored Tablet - 60	1 tablet <u>od</u>	1.5 tablets <u>od</u>	2 tablets <u>od</u>	2.5 tablets <u>od</u>	3 tablets <u>od</u>	
	3-4.9kg	5-6.9kg	7-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg
ABC (20 mg/ml) Oral Solution - 240	2 ml bd	3 ml bd	4 ml bd	6 ml bd	8 ml bd	10ml bd
ABC (60 mg) Dispersible Tablet - 56	<i>Not Recommended**</i>			2 tablets bd	2.5 tablets bd	3 tablets bd
3TC (50/5 mg/ml) Oral Solution - 240	2 ml bd	3 ml bd	4 ml bd	6 ml bd	8 ml bd	15 ml bd

*Please note the table above has been simplified, kindly refer to the [Republic of South Africa: 2019 ART Clinical Guidelines](#), to access the comprehensive dosing chart.

* ABC 60mg tablet (dispersible) dosing is not recommended to start until 10kg for clarity*

The quotations received for Abacavir 120mg, Lamivudine 60mg dispersible, scored, tablets also represent a lower price than for the single agents currently available on tender. Further details can be seen in Table 4.

Table 4: Estimated Annual Cost of Treatment Comparison

Product	3-5.9kg	6-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg
ABC/3TC (120/60mg) Dispersible, Scored Tablets	R732,13	R1 098,19	R1 464,26	R1 830,32	R2 196,39
ABC (20 mg/ml) Oral Solution + 3TC (50/5 mg/ml) Oral Solution	R940,48	R1 253,98	R1 880,97	R2 507,96	R3 450,97
ABC (60 mg) Tablet (Disp) + 3TC (50/5 mg/ml) Oral Solution	<i>Not Recommended*</i>		R1 824,89	R2 312,72	R3 116,57

Source: Delivery price for ABC and 3TC singles: Master Procurement Catalogue, May 2021

* ABC 60mg tablet (disp) dosing is not recommended to start until 10kg