

National Department of Health, South Africa



Abacavir/Lamivudine 120mg/60mg Dispersible, Scored Tablets

Training Slides

Information for healthcare workers

August 2021

Introducing Abacavir/Lamivudine (ABC/3TC) 120mg/60mg dispersible, scored tablets: an optimal product that is just as effective as the single formulations for ABC and 3TC, but in a fixed-dose combination (FDC)

WHY ARE ABC/3TC 120MG/60MG DISPERSIBLE, SCORED TABLETS BEING INTRODUCED?

The two NRTIs, ABC (abacavir) and 3TC (lamivudine), form the backbone of first line ART for paediatric and adolescent patients. NRTIs, like ABC and 3TC, combat HIV replication by blocking the HIV reverse transcriptase enzyme, thus preventing HIV replication.

For paediatric patients who weigh 3 – 24.9kg the **single formulations for ABC and 3TC** are currently the **preferred NRTI options**:

- The single formulations for these patients are mostly **administered twice a day** in combination with other ARVs.
- The **twice a day dosing** of the ABC and 3TC single formulations in this weight band leads to administration issues, and subsequent **pitfalls in retention in care and viral suppression**.



The ***once-a-day dosing of ABC/3TC dispersible, scored tablets*** aims to address these issues by ***greatly simplifying the dosing and administration*** of ABC and 3TC across multiple weight bands from 3 – 24.9kg.

NOTE: ABC/3TC 120mg/60mg dispersible, scored tablets can be prescribed by a doctor or a professional nurse.

Which ABC and 3TC single formulations are being replaced by ABC/3TC dispersible, scored tablets?

INDICATIONS FOR ABC/3TC 120mg/60mg dispersible, scored tablets:

In combination with other antiretrovirals, for the treatment of HIV in children **3 – 24.9kg**.
The ability to take this product **once a day** across a wide weight band will greatly simplify the dosing.



PAEDIATRIC PRODUCT	CHILD'S WEIGHT: 3 – 24.9kg
<i>The child is currently on a combination of one of these products</i>	Should the product be replaced by ABC/3TC 120mg/60mg dispersible tablets?
ABC (20mg/ml) oral solution	YES
3TC (10mg/ml) oral solution	
ABC (60mg) dispersible tablet	

NOTES ON ABC AND 3TC TABLET FORMULATIONS:

- Patients in the 10 – 24.9kg weight band can still take paediatric ABC 60mg dispersible tablets.
- Patients in the 14 – 24.9kg weight band can still take adult tablets for ABC and 3TC.

Advantages of ABC/3TC dispersible, scored tablets

ABC/3TC dispersible, scored tablets were developed as an alternative and optimal, combined formulation for ABC and 3TC syrups and ABC paediatric tablets in young children because:



- ✓ ABC/3TC dispersible, scored tablets only need to be administered once a day and thus further decrease the pill burden and improve adherence.
- ✓ ABC/3TC dispersible, scored tablets are easily mixed with a small amount of water and are easy to swallow.
- ✓ ABC/3TC dispersible, scored tablets are cheaper than the single ABC and 3TC formulations for patients in the lower weight bands.

There are multiple ABC and 3TC single formulations with varying dosing frequencies across the weight bands; ABC/3TC dispersible, scored tablets greatly simplify the regimen dosing across multiple weight bands

CURRENT PAEDIATRIC SINGLE FORMULATION REGIMENS DOSING CHART

Product	3-4.9kg	5-6.9kg	7-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg
ABC (20 mg/ml) Oral Solution	2 ml bd	3 ml bd	4 ml bd	6 ml bd OR 12 ml od	8 ml bd OR 15 ml od	10 ml bd
ABC (60 mg) Dispersible Tablet	<i>Not recommended for children <10kg</i>			2 tablets bd OR 4 tablets od	2.5 tablets bd OR 5 tablets od	3 tablets bd
3TC (10mg/ml) Oral Solution	2 ml bd	3 ml bd	4 ml bd	6 ml bd OR 12 ml od	8 ml bd OR 15 ml od	15 ml bd OR 30 ml od

Please note the table above has been simplified and does not include combinations of paediatric formulations with adult formulations, kindly refer to the [Republic of South Africa: ARV Drug Dosing Chart for Children 2021](#), to access the comprehensive dosing chart.

ABC/3TC dispersible, scored tablets only need to be given **once a day**. This **greatly simplifies the dosing schedule** across multiple weight bands.

ABC/3TC DISPERSIBLE, SCORED TABLETS DOSING CHART

Product	3-5.9kg	6-9.9kg	10-13.9kg	14-19.9kg	20-24.9kg
ABC/3TC (120/60 mg) Dispersible, Scored Tablet	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>

Demonstration on the use of ABC/3TC dispersible, scored tablets

As this is a new product, it is **mandatory** that the healthcare workers carefully **explain** and **demonstrate** to caregivers how to administer ABC/3TC dispersible, scored tablets in combination with other ARVs.

Adequate instructions must be provided to the caregiver to ensure:

- ✓ the correct number of tablets are given
- ✓ the entire dose is administered as required

ABC/3TC 120mg/60mg tablets are dispersible and scored, this means that they can be mixed with a small amount of water before administration, and that they can be split/crushed to accommodate dosing where half a tablet is required.

- Only a small amount of **water** is required - mixing the tablets with **10ml (2 teaspoons)** of water is recommended

Note: ABC/3TC dispersible, scored tablets can also be swallowed whole (without crushing or mixing the tablets with water) for children who are able to swallow tablets


NOTE: Healthcare workers must **ask the caregiver about how they give the ABC/3TC dispersible, scored tablets** in combination with other ARVs when they come back for follow up visits to ensure that administration is as per the guidelines, and to ensure that the child is getting the correct, therapeutic dose of the ABC/3TC tablets.

How to administer ABC/3TC dispersible, scored tablets with water

- ABC/3TC dispersible, scored tablets can be dissolved and mixed in a small amount of water prior to administration.
- ABC/3TC dispersible, scored tablets can also be split/crushed before mixing them with water.

STEP 1: DETERMINE THE DOSE

Add the correct number of ABC/3TC tablets to a clean, empty glass or cup based on the child's weight. (See Dosing Table)

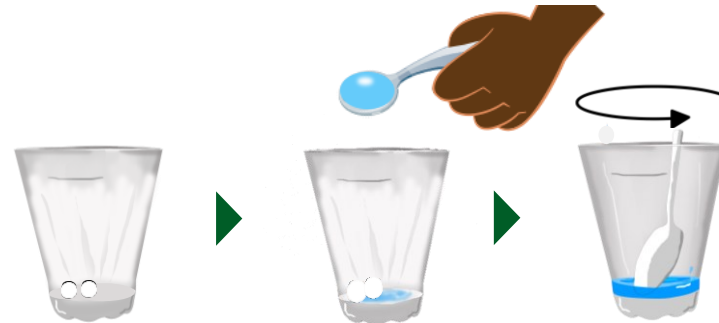


Weight	No. of ABC/3TC (120/60 mg) Daily Tablets
3 – 5.9kg	1
6 – 9.9kg	1.5
10 – 13.9kg	2
14 – 19.9kg	2.5
20 – 24.9kg	3

TIP: If you are administering 1.5 or 2.5 tablets, you can easily split the ABC/3TC tablet down the middle on the solid line.

STEP 2: PREPARE THE ABC/3TC MIXTURE

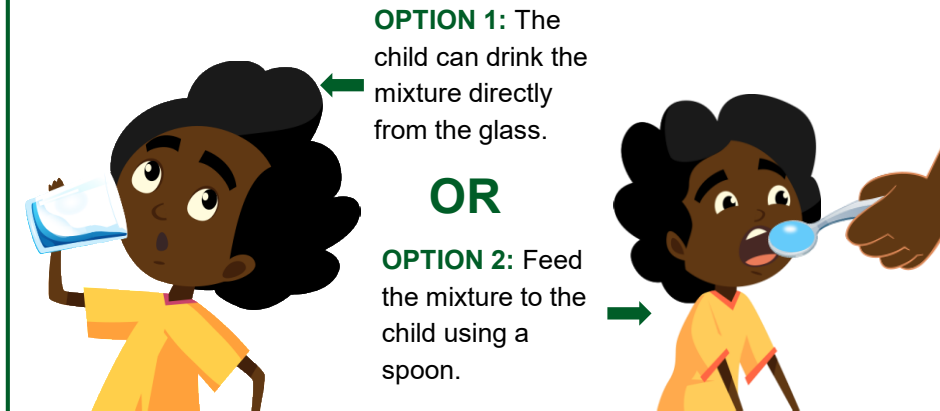
Add 10mL (2 teaspoons) of clean water into the glass or cup and stir until the tablets dissolve.



TIP: If the tablets do not dissolve completely (i.e., they lump together), stir and slowly add another 10ml (2 teaspoons) of extra water until the tablets fully dissolve.

STEP 3: GIVE THE MIXTURE TO THE CHILD

Give the medicine to the child to drink. Make sure they drink all the medicine right away or within a maximum of 30 minutes.



OPTION 1: The child can drink the mixture directly from the glass.

OR

OPTION 2: Feed the mixture to the child using a spoon.

TIP: If any medicine remains in the glass, add a little more water to the glass and give it to the child. Repeat until no medicine remains in the glass.

Possible adverse effects of ABC/3TC dispersible, scored tablets

NOTE: If a patient has never experienced an adverse event / side effect on their current ABC and 3TC single formulations, they will not experience any adverse effects from the ABC/3TC dispersible, scored tablets.

Like the single formulations of ABC and 3TC, ABC/3TC dispersible, scored tablets are **safe**, but **adverse events / side-effects can occur** in patients newly initiated on **any** ABC and 3TC formulations.

- **ABC specific adverse events: Hypersensitivity reactions** are serious and can occur within the first 6 weeks of therapy but are uncommon. These symptoms typically worsen in the hours immediately after the dose and after each subsequent dose. If a hypersensitivity reaction is suspected and no alternative explanation is found, ABC must be stopped and never given again. Substitute ABC with another ARV if ABC hypersensitivity reaction is suspected.
- **3TC specific adverse events:** 3TC can cause **pure red cell aplasia** which presents as **anaemia**, but this is very rare.

It's important to observe infants and young children periodically for any adverse events, and to report them to your healthcare facility.

POSSIBLE SYMPTOMS OF ABC HYPERSENSITIVITY REACTION:

- | | |
|---|--|
| <ul style="list-style-type: none">• Fever• Rash• Nausea• Vomiting• Diarrhea | <ul style="list-style-type: none">• Abdominal pain• Fatigue• Sore throat• Shortness of breath• Cough |
|---|--|



**REPORT ANY OF THESE
SYMPTOMS TO YOUR NEAREST
HEALTH FACILITY**

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

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

National HIV and TB Care Worker Hotline: 071 840 157

- This helpline can be contacted via SMS / Please Call Me / WhatsApp

Right To Care Paediatric, Adolescent and Adult HIV Helpline: 082 352 6642

- This helpline can be contacted via SMS / Please Call Me / WhatsApp

KZN Paediatric Hotline: 0800 006 603

Weight based dosing for all other paediatric formulations are available on [KnowledgeHub](#) in the 2019 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates, October 2019