health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Reference: 2026/07/17/EDP/01

NOTICE: AVAILABILITY OF PAEDIATRIC ABACAVIR/LAMIVUDINE/DOLUTEGRAVIR (ABC/3TC/DTG) 60mg/30mg/5mg FIXED-DOSE COMBINATION DISPERSIBLE TABLETS (pALD)

The South African Government is committed to providing simplified antiretroviral treatment (ART) options to all patients including children. This is done to ensure access to treatment for children with different needs with the aim of achieving and sustaining optimal viral suppression while avoiding complex treatment regimens, high pill burdens, and caregiver fatigue.

In 2024 the South African Health Products Regulatory Authority (SAHPRA) registered a paediatric ABC/3TC/DTG (60/30/5mg) fixed-dose combination dispersible tablet (pALD). This paediatric combination is now included as a first-line regimen for children. This means a transition from separate formulations — paediatric dolutegravir 10mg (pDTG) and paediatric abacavir/lamivudine 120/60 mg (pABC/3TC) to the 3-in-1 fixed-dose combination (pALD), once-daily dispersible tablet/s. This transition represents a significant advance in paediatric HIV care with the potential to enhance treatment adherence and improve health outcomes for children living with HIV.

This is the second circular to describe the transition of children to pALD, the first circular (reference: 2026/01/19/EDP/01) was retracted (reference 2026/03/23/EDP/01) due to stock issues.

This circular supersedes the previous circulars, and serves to inform provinces, districts, clinical managers, pharmacists, and healthcare workers of pALD availability, clinical indications, dosing guidance, transition planning, and procurement considerations.

Product Overview

pALD (60/30/5mg) dispersible tablet is the first-ever triple fixed-dose combination containing DTG for children living with HIV. It is clinically equivalent to the separate components pDTG (10mg) + ABC/3TC (120/60mg) and represents a formulation improvement rather than a regimen change.

Product Specifications	
Tablet Strength	ABC/3TC/DTG (60/30/5mg)
Formulation	Dispersible tablets (not scored)
Administration	Dispersed in water, taken orally once daily
Taste	Strawberry cream flavoured
Target Population	• Children 2 to 20kg • pDTG 10mg dispersible/scored tablets will still be needed for children coinfected with TB, with contraindications to ABC and those on second- and third-line treatment regimens. • ABC/3TC 120/60 tablets will still be needed for patients on second- and third-line treatment regimens and for neonates ≥ 2.0 KG and ≥ 37 weeks gestational age.

Clinical Advantages:

- Optimal, once-daily dosing
- Easier administration for caregivers
- Supports improved adherence and viral suppression
- Simplifies supply chain management (one product instead of two)

Indications:

pALD is recommended for: Children living with HIV weighing 2kg (providing that the child has a chronological age of ≥ 4 weeks and a corrected gestational age of ≥ 37 weeks) up to 20kg either on ABC/3TC + pDTG or starting ART.

- Children between 20-24.9kg should be given DTG 50mg + pABC/3TC (three 120/60mg tablets) once daily. Those who are unable to swallow DTG 50mg can use either pDTG (three 10mg tablets) and pABC/3TC (three 120/60mg tablets) once daily, or pALD (six 60/30/5mg tablets once daily).
- Children ≥ 25 kg should transition to **ABC/3TC 600/300mg + DTG 50mg or the FDC ABC/3TC/DTG (600/300/50mg) (as per NDoH dosing chart)**.
- Children ≥ 25kg should not be prescribed pALD.
- DTG interacts with the TB medicine rifampicin (RIF). Children receiving TB treatment containing RIF should be given an additional dose of DTG equivalent to their standard daily dose of DTG for the duration of TB treatment. The two doses should be given 12 hours apart.

Table 1: Dose of pALD

Weight band	Dose of pALD (60/30/5mg)
2* – 5.9kg	One tablet once daily
6 – 9.9kg	Three tablets once daily
10 – 13.9kg	Four tablets once daily
14 – 19.9kg	Five tablets once daily
20 - < 24.9kg	*Six tablets once daily* **pABC/3TC (three 120/60mg tablets) + DTG 50mg once is the preferred regimen for this weight band**

*Providing that the child has a chronological age of ≥ 4 weeks and a corrected gestational age of ≥ 37 weeks

For additional details regarding management of children living with HIV, including neonates, please consult the Essential Medicine List (EML) Standard Treatment Guidelines (STGs), available online at https://www.health.gov.za/nhi-edp-stgs-eml/, or the 2026 National Consolidated HIV Guidelines (https://knowledgehub.health.gov.za/elibrary/national-consolidated-guidelines-management-hiv-adults-adolescents-children-infants-and).

Transition Plan for paediatric abacavir/lamivudine/dolutegravir (pALD) Implementation

Phase 1: (5 months) – September 2026 to March 2027

- New ART initiations without contraindications to abacavir or dolutegravir
- Excludes neonates who should be initiated on other combinations of ABC, 3TC & DTG (term infants) or on other regimens (preterm infants)

Phase 2 (7 months) – April to August 2027

- Gradual scale-up of pALD reaching 90% of children 2 to 19.9kg on an ABC/3TC/DTG regimen
- Children weighing 20-24.9kg are excluded from transitioning to pALD, as they are eligible to switch to DTG 50mg

Supplier capacity and stock management considerations have been built into the transition plan to prevent wastage.

Procurement of Paediatric Abacavir/Lamivudine/Dolutegravir (pALD)

pALD is available for procurement on the ARV tender (HP13-2025ARV).

Table 2: Product summary for Abacavir/Lamivudine/Dolutegravir 60/30/5mg tablets:

Product description	Cost per pack	Supplier(s)	NSN
Abacavir 60mg, Lamivudine 30mg, Dolutegravir 5mg	R53.33	Cipla	222001658

For further assistance on how and when to use this formulation please contact:
National HIV & TB Health Care Worker Hotline: 0800 212 506 or 021 406 6782
National HIV & TB Health Care Worker Hotline: 071 840 1572
- This helpline can be contacted *via* SMS/Please call me/WhatsApp

HIV Expert Helpline 082 352 6642
- This helpline can be contacted via call/SMS/Please call me/WhatsApp

KZN Paediatric Hotline:
The helpline can be contacted via VULA – Paediatric Infectious Diseases KZN

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:
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Kind regards

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DATE: 31/7/2026

LJ Bamford

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ACTING CHIEF DIRECTOR: MATERNAL, CHILD AND WOMEN'S HEALTH
DATE: 28th July 2026