



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Reference: 2022/11/22/EDP/01

NOTICE: AVAILABILITY OF NEW ANTIRETROVIRAL PRODUCTS: PAEDIATRIC DOLUTEGRAVIR 10mg, ABACAVIR/LAMIVUDINE/DOLUTEGRAVIR 600/300/50mg, AND DARUNAVIR/RITONAVIR 400/50mg

Paediatric dolutegravir 10mg dispersible, scored tablets:

Following registration with the South African Health Products Regulatory Authority (SAHPRA), Dolutegravir (DTG) 10mg dispersible, scored tablets are now recommended as part of the standard first-line antiretroviral regimen for children (≥ 4 weeks to <10 years of age) in the weight band 3 – 20 kg. The benefits of DTG 10mg dispersible, scored tablets (pDTG) include increased clinical efficacy, better side effect profile, ease of administration and improved palatability. The pDTG tablets replaces Lopinavir/ritonavir and children should be switched to the DTG 50mg formulation after 20kg, unless there are challenges swallowing whole tablets.

For children on Abacavir (ABC) and Lamivudine (3TC) that are in the weight bands of 3-24.9kg and over 4 weeks old, it is recommended to consider co-administering pDTG with ABC/3TC 120/60mg dispersible, scored tablets to simplify the administration as they both can be dispersed in the same solution. More information on ABC/3TC 120/60mg dispersible, scored tablets can be found on the NDOH Knowledge Hub eLibrary through the following link:

<https://www.knowledgehub.org.za/elibrary/abacavirlamivudine-abc3tc-120mg60mg-dispersible-scored-tablets-job-aid-and-training-slides>.

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 are currently being updated to reflect this recommendation. These updated documents will be communicated once they have been finalised. In the interim, dosing of pDTG is shown in Table 1, and dosing of ABC/3TC 120/60mg is shown in Annexure A.

Please note that as with other DTG formulations, the dose needs to be adjusted with concomitant use of rifampicin. See Table 1 below for dose recommendations according to weight.

Table 1: Dosing of Dolutegravir 10 mg dispersible, scored tablets (with or without concomitant Rifampicin) by weight

| DOLUTEGRAVIR 10MG DISPERSIBLE, SCORED TABLETS | | |
|---|--|--|
| | DOLUTEGRAVIR DOSE, NO RIFAMPICIN USAGE | DOLUTEGRAVIR DOSE WHEN USING CONCOMITTANT RIFAMPICIN |
| Target dose | By weight band ONCE daily | By weight band TWICE daily |
| <i>Weight (kg)</i> | | |
| 3 – 5.9 | ½ x 10mg tablet daily | ½ x 10mg tablet, twice a day |
| 6 – 9.9 | 1 ½ x 10mg tablets daily | 1 ½ x 10mg tablets, twice a day |
| 10 – 13.9 | 2 x 10mg tablets daily | 2 x 10mg tablets, twice a day |
| 14 – 19.9 | 2 ½ x 10mg tablets daily | 2 ½ x 10mg tablets, twice a day |
| 20 – 24.9 | 3 x 10mg tablets OR 1 x 50mg tablet daily | 3 x 10mg tablets, twice a day OR 1 x 50mg tablet, twice a day |

Procurement of Dolutegravir 10mg dispersible, scored tablets

Provinces can procure these items as a buy-out at their discretion. To facilitate this process, quotations have been obtained (see Table 2 below, and Annexure 2 for Provincial Procurement Quotation).

Table 2: Product summary for Dolutegravir 10mg dispersible tablets:

| Product description | Supplier (s) | Quantity Quoted | Cost per pack (per quotation) | Lead Times | NSN |
|---|------------------------------------|-----------------|-------------------------------|------------|-----------|
| Dolutegravir 10mg dispersible; 30 tablets | Viatrix Healthcare (Pty) Ltd | 92 000 | R31.05 | 56 days | 222001370 |
| | Macleods Pharmaceuticals (Pty) Ltd | 92 000 | R36.60 | 112 days | |

Abacavir/Lamivudine/Dolutegravir (ALD) 600/300/50mg combination tablets:

The recently released HP13-2022 ARV contract circular (*HP13-2022ARV: Supply and delivery of anti-retroviral medicines to the Department of Health for the period 1 July 2022 to 30 July 2025*), contains the fixed dose combination consisting of **Abacavir 600mg/Lamivudine 300mg/Dolutegravir 50mg (ALD)**. Utilisation of ALD will simplify daily dosing for adult patients and children ≥ 25 kg, which has been shown to be beneficial to patient adherence on antiretrovirals (ARVs), see Table 3 for further details.

Table 3: Product summary for Abacavir/Lamivudine/Dolutegravir 600/300/50mg tablets:

| Product description | Cost per pack | Supplier(s) | NSN |
|---|---------------|------------------------|-----------|
| Abacavir 600mg, Lamivudine 300mg, Dolutegravir 50mg | R170.69 | Emcure 60% split | 222000210 |
| | R243.04 | Cipla Medpro 40% split | |

Darunavir/ritonavir 400/50mg combination tablets:

Furthermore, the HP13-2022 ARV contract circular also contains the fixed dose combination of Darunavir(DRV)/ritonavir(r) 400/50mg, used in third line antiretroviral therapy. This product is replacing the DRV 400mg standalone product, which is no longer available on contract. The reason for this decision is that DRV cannot be used without the addition of ritonavir, and the combination

DRV/r product will decrease pill burden for the patient. Utilisation of this product will also simplify daily dosing for those adult patients who are currently taking DRV/r 800/100mg using single agents. This will be beneficial to patient adherence on ARVs, see Table 4 for further details

Table 4: Product summary for Darunavir/ritonavir 400/50mg tablets:

| Product description | Cost per pack | Supplier | NSN |
|---|---------------|------------------|-----------|
| Darunavir 400mg, Ritonavir 50mg tablet, 56/60 tablets | R380.29 | Mylan 100% award | 222001258 |

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


Implementation queries:

Adult HIV Programme: Ms Letta Seshoka(letta.seshoka@health.gov.za)

Paediatric and Adolescent HIV programme: Ms Tabisa Silere-Maqetseba (Tabisa.Silere-Maqetseba@health.gov.za)

PMTCT :Ms. Mathilda Ntloana (Mathilda.ntloana@health.gov.za)

Kind regards



MS K JAMALOODIEN
DIRECTOR: AFFORDABLE MEDICINES
DATE: 09/12/2022



DR T CHIDARIKIRE
ACTING CHIEF DIRECTOR: HIV/AIDS
DATE: 12.12.2022

ANNEXURE 1: RECOMMENDED DAILY DOSING FOR ABC/3TC and DTG FORMULATIONS

| Formulations and Number of Pills per Weight Band | | | | | | |
|--|--|--|--|---------------------------------------|----------------------------------|----------------------------------|
| Weight (Kgs) | ABC/3TC 120/60mg dispersible, scored tablet ¹ | DTG 10mg dispersible, scored tablet ^{1 & 2} | ABC/3TC 600/300 mg tablet ⁴ | DTG 50 mg tablet ^{2 & 5} | ABC/3TC/DTG 600/300/50 mg tablet | TDF/3TC/DTG 300/300/50 mg tablet |
| 3 – 5.9 | 1 | 0.5 | – | – | – | – |
| 6 – 9.9 | 1.5 | 1.5 | – | – | – | – |
| 10 – 13.9 | 2 | 2 | – | – | – | – |
| 14 – 19.9 | 2.5 | 2.5 | – | – | – | – |
| 20 – 24.9 | 3 | [Transition to DTG 50mg] ³ | – | 1 | – | – |
| 25 – 29.9 | [Transition to ABC/3TC 600/300mg] ³ | – | 1 | 1 | 1 | – |
| ≥30 | – | – | 1 | 1 | 1 | 1 |

1. Can be dissolved in the same solution
2. Twice daily with concomitant use of rifampicin
3. If able to swallow whole tablets
4. Transition to ABC/3TC/DTG if eligible
5. Transition to ABC/3TC/DTG or TDF/3TC/DTG if eligible

ANNEXURE 2: PROVINCIAL PROCUREMENT QUOTATION



Private Bag X828, PRETORIA, 0001. DR AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA 0187
Directorate: Affordable Medicines Tel: (012) 395 8130

To: Depot Managers; Heads of Pharmaceutical Services

PPQ24/2022: Dolutegravir 10mg dispersible tablet, 30 tablets

In an effort to assist the provinces, NDoH have solicited quotations from the only registered supplier, aligned with the Five Pillars of Procurement contained in the Public Finance Management Act, 1999. (*Value for Money / Open and Effective Competition / Ethics and Fair Dealing / Accountability and Reporting / Equity*).

We have sourced a quotation from supplier relating to Dolutegravir 10mg dispersible Tablet; 30 Tablets; the quotation is listed below.

| Dolutegravir 10mg dispersible Tablet; 30 Tablets | | | | |
|---|------------------------------------|------------------------|-------------------------------------|--|
| | Company name | Quantity Quoted | Per Pack Price Incl. Vat | Comment |
| 1. | Viatrix Healthcare (Pty) Ltd | 92 000 | R31.05 | Recommended • Stock available within 28 days lead time on Section 36. • Registered product stock available within 56 days lead time. |
| 2. | Macleods Pharmaceuticals (Pty) Ltd | 92 000 | R36.60 | Recommended • Stock available within 112 days lead time. |

If you have any queries, please contact Babalwa.Melitafa@health.gov.za

Yours sincerely

KHADIJA JAMALOODIEN
DIRECTOR: AFFORDABLE MEDICINES
DATE: 22/11/2022