≥2.0 kg and ≥35 weeks gestational age at birth

Birth to <4 weeks of age

≥3.0 kg AND ≥4 weeks of age

AZT + 3TC + NVP → **ABC + 3TC + DTG**

Baseline Assessment

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV.

Review after 1 week then 1-2 weekly

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections

Review when 4 weeks of age

- Clinical review and counselling
- If <3 kg, assess reasons for poor weight gain & manage appropriately, continue ART with AZT (12 mg/kg/dose twice daily) + 3TC (4 mg/kg/dose twice daily) + NVP (6 mg/kg/dose twice daily) until ≥3.0 kg
- If >3 kg, switch ART to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring as per ***"Monitoring on ART" on page 19***

	Zidovudine (AZT)		Lamivudine (3TC)		Nevirapine (NVP)	
Available formulation	Solution 10 mg/mL		Solution 10 mg/mL		Solution 10 mg/mL	
Weight (kg) at birth	Dose		Dose		Dose	
	AM	PM	**AM**	**PM**	AM	PM
≥2.0 – <3.0	10 mg (1 mL)	10 mg (1 mL)	5 mg (0.5 mL)	5 mg (0.5 mL)	15 mg (1.5 mL)	15 mg (1.5 mL)
≥3.0 – <4.0	15 mg (1.5 mL)	15 mg (1.5 mL)	8 mg (0.8 mL)	8 mg (0.8 mL)	20 mg (2 mL)	20 mg (2 mL)
≥4.0 – <5.0	20 mg (2 mL)	20 mg (2 mL)	10 mg (1 mL)	10 mg (1 mL)	30 mg (3 mL)	30 mg (3 mL)

<2.0 kg
OR
<35 weeks gestational age at birth

Birth to < 4 weeks of age
OR < 3 kg

≥ 4 weeks of age
AND
≥ 3 kg

AZT + 3TC + NVP → **ABC + 3TC + DTG**

Baseline Assessment

- Clinical review
- Bloods: confirmatory HIV PCR (or HIV VL), CD4 count, FBC +/- HIV drug resistance test if mother failing treatment on TLD2 or a protease inhibitor regimen
- Counsel parent / caregiver
- Ensure the mother is on ART, and advise that breastfeeding is recommended for all infants living with HIV

Review after 1 week then 1-2 weekly

- Clinical review and counselling
- Check baseline blood results
- If indeterminate / negative confirmatory HIV PCR test result, refer to Guideline for Family-Centered Transmission Prevention of Communicable Infections
- Monitor weight gain and adjust ARV doses

Review when ≥4 weeks of age

- Clinical review and counselling
- If <3 kg, continue AZT + 3TC + NVP
- If >3 kg, switch to ABC + 3TC + DTG (refer to ARV dosing chart for doses)
- Continue monitoring and evaluations as per ***"Monitoring on ART" on page 19***

Gestational age at birth	Chronological age	Zidovudine (AZT)	Lamivudine (3TC)	Nevirapine (NVP)
		Solution 10 mg/mL	Solution 10 mg/mL	Solution 10 mg/mL
< 30 weeks	Birth - < 4 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 4 weeks - < 8 weeks	3 mg/kg/dose twice daily	4 mg/kg/dose twice daily	4 mg/kg/dose twice daily
	≥ 8 weeks - < 10 weeks	12 mg/kg/dose twice daily		6 mg/kg/dose twice daily
≥ 30 - < 35 weeks	Birth - < 2 weeks	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily	2 mg/kg/dose twice daily
	≥ 2 - < 4 weeks	3 mg/kg/dose twice daily		4 mg/kg/dose twice daily
	≥ 4 - < 6 weeks		4 mg/kg/dose twice daily	6 mg/kg/dose twice daily
	≥ 6 - < 8 weeks	12 mg/kg/dose twice daily		

When weight is ≥2 kg and ≥35 weeks corrected gestational age, review ARVs and refer to table ***"ART for the Term Neonate" on page 28***

Annexure 3 *Enhanced Adherence Counselling*

Source: Differentiated Care Models Standard Operating Procedures 2023

ENHANCED ADHERENCE COUNSELLING SESSIONS

There are two sessions:
Session 1: Initial enhanced adherence counselling for patients struggling with adherence.
Session 2: Enhanced adherence counselling for persistent non-adherent patients (covered in DMOC SOP 2).

SESSION 1

Benefits of Viral Suppression:

- Undetectable VL means the virus is untransmittable to HIV negative partners
- CD4/immune function recovery
- Less chance of illness
- Reduced visits to clinic through access to MMD/RPC

1. Explain the purpose of your session, define terms:

- Determine possible reasons for abnormal assessment results.
- Assess and address any reported barriers to adherence and discuss effective strategies to overcome.
- Update or develop an adherence plan with the patient.

2. Education on the assessment result

- Assess patient for mental health using the Mental Health Assessment tool in Annexure II.
- Find out what treatment education the patient has received. Recap the benefits of VL suppression as outlined in the box above.
- Find out what the patient knows about the treatment they are taking and check the treatment regimen has been understood correctly i.e. when each medicine is taken.
- Explain in a supportive way that the most common reason for such result is a problem with taking medication correctly.
- Find out if the patient received education on the assessment to check adherence and effective treatment(VL/BP/HbA1c) and its meaning. If not, provide this information (see SOP 1: FTIC session 2).

3. Flexibility on treatment

- Clear any myths and misconceptions around taking treatment and explain that there is some flexibility.
- Emphasize the importance of patients choosing their own suitable time for taking medication as prescribed.
- Explain what to do with late or missed doses depending on the treatment.
- Explain what to do in case of alcohol use while on treatment. If patient cannot control their use of alcohol, they should make sure that they take their treatment anyway.
- Explain to patient that it is better not to use traditional medicines that could interfere with the treatment. If they take traditional medicine, they should make a plan with the clinician to still take their treatment.

4. Patient's experiences

Ask: What makes it difficult for you to take the treatment sometimes? Encourage the patient to be honest about personal issues that may affect their adherence and help them to address issues such as alcohol or other substance intake as they can lead to forgetting medication.

- Explain that medication should be taken even without food and what they can do if food insecurity is an issue. Inform and assist patient on how to access government support programmes, if necessary.
- Consider patient's religious and traditional beliefs that may contribute to non-adherence to treatment.

5. Identify strategies to ensure good adherence

Ask: What could help you to remember to take the treatment?

Discuss treatment reminders and adherence options including the advantages and disadvantages of each for the specific patient:

- Treatment buddy to remind the patient to take treatment
- Setting phone alarm
- Support by a family member
- Pill counts
- Marking a calendar or using a pill box
- Linking medication to meals times or other daily routine such a brushing teeth
- Storing medication somewhere accessible if unable to disclose to others in the home
- Carrying/keeping spare medication to take at work in case dosing at home was forgotten or client late returning home
- Modified Direct Observed Therapy such as treatment supporter (this is also applicable to children)

Ask: Who could support you to take the treatment every day?

Discuss sources of social support for the client. Emphasise the importance of support structures in coping and adherence such as family, friends, peer support groups, faith-based group and work-based support.

- Encourage sharing of feelings and emotions regarding the illness.
- Empower the patient in making a plan that is adapted to the barriers expressed. Be aware not to create dependency, but to find their own solutions, with the help of the healthcare worker or lay counsellor.

6. Inform the patient about pathway ahead

- Explain further assessments (tests) to check adherence and effective treatment as per disease specific guidelines (for HIV: a further viral load will be taken in 3 months, for hypertension: a BP will be taken at every visit for the next 3 months, for diabetes: a further HbA1c test will be done in 3 months)
- Explain that if the next assessment is normal, it will become easier to collect treatment. The patient can ask and the clinician should offer and enroll the patient into a simpler treatment supply collection system of their choice with longer treatment supply based on what is available at the facility (FAC-PUP/Adherence Club/EX-PUP).

Annexure 4 *Mental Health Assessment*

Source: Differentiated Care Models Standard Operating Procedures 2023

As mental health disorders can impact adherence negatively, it is recommended that screening is provided for mental health disorders while treating HIV, TB and NCDs.

Basic screening should assess:

1. What is the patient's appearance?

- Is he/she clean and looking after him or herself
- Does the person look worried or sad?
- Does the person seem agitated?
- Does he/she seem suspicious, nervous or hostile?

2. Assess the patient's mood, asking:

- How have you been feeling over the last week?
- Have you been feeling mostly normal, or sad or happy, or worried?
- How do you feel today?
- What are your feelings about the future?

3. Assess the patient's thoughts:

- Are you having negative thoughts?
- Are you having strange thoughts?
- Any unusual fears (such as being followed, spied on)?
- Have you had any strange experiences (such as hearing voices/seeing visions other people cannot hear or see) or special abilities?

Negative thoughts can suggest depression, other strange thoughts or experiences could raise suspicion of psychosis.

4. Assess patient's cognition:

- Does thinking seem slow?
- Is the person able to concentrate?
- Does the memory seem impaired?

If you suspect a mental health disorder while asking the previous questions, try to answer the following questions:

- What is the main problem?
- How long has it been present?
- Does it affect the patient's daily functioning?
- Can this be managed at this clinic?

If further assessment and treatment cannot be provided at the clinic, refer to a psychiatric nurse or service. Tools such as SRQ 20 recommended by the WHO can help to identify mental health disorder.

Provide the patient with education on mental health and provide them with advice that can help them overcome symptoms. Explain to the patient that the following signs could mean that they may need support to improve their mental health condition:

If they feel:

- constantly angry or very worried
- very sad for a very long time
- they are losing interest in things they used to enjoy doing
- they can not cope with work or daily activities
- their mind is controlled (such as by voices) or out of control
- they need to use alcohol or drugs
- Obsessively do things such as repeat washing hands, non-stop sport activity, eating too much, obsessive diet or other obsessive behaviours.
- Hurt themselves or other people or destroy things.
- Do irresponsible things that could harm them or others.
- Having problems sleeping or feeling tired and not having energy.
- Feeling anxious, looking or feeling 'jumpy' or upset, having panic attacks.
- Not wanting to spend time with people; spending too much time in bed.
- Hearing and seeing things that others do not see.

Other differences in the way the person sees what is happening around them, for example believing that someone is trying to harm you, or laughing at you.

If the patients show signs of intense sadness, risk to harm themselves or others or hear or see things that others do not see they should directly be referred for psychiatric support.

If the patients experience some of the other symptoms, explain to them that they can identify some ways to help them cope with their situation by telling them that it might help to:

- Share your feelings and spend time with other people you trust.
- Get back to daily routine as much as possible (such as work, school, housework).
- Participate in religious or spiritual activities.
- Play sports or get regular exercise.
- Eat regular meals.
- Get adequate rest.
- Take a break and relax.
- Participate in enjoyable activities (such as singing, dancing, reading), even if at the moment it may be hard for you to enjoy them.
- Help other people talk about how they feel, but also respect if they choose not to talk about it.

Recommend that they avoid:

- Using alcohol or drugs to cope with the symptoms
- Withdrawing from family and friends
- Withdrawing from daily activities
- Overworking
- Blaming yourself or others
- Neglecting your health or self-care (such as sleep, hygiene, diet)

Explain that the patient, may need to seek help from a psychiatric nurse, social worker, psychologist or counsellor if they want to talk with someone outside of their family or circle of friends or if their symptoms do not improve with coping strategies.

ARV Drug	Formulations (as used in dosing chart)	Can tablets/capsules be split/crushed/ opened if unable to swallow?	Comment
Abacavir (ABC)	Oral solution: 20 mg/ml Tablets: 60 mg, 300 mg FDC tablets: ABC/3TC 120/60 mg; ABC/3TC 600/300 mg; ABC/3TC/DTG 600/300/50 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg	Tablets: **YES** FDC 120/60 mg tablet is a dispersible tablet. May be split/crushed. FDC capsules should be opened and contents added to a small amount of food or dispersed in a liquid.	Hypersensitivity reaction (fever, rash, GIT & respiratory symptoms) may occur during first 6 weeks of therapy, very uncommon in black African patients. Symptoms typically worsen in the hours immediately after the dose and after each subsequent dose. Caregivers or patients should discuss symptoms early with the clinician rather than stopping therapy. Stop ABC permanently if hypersensitivity reaction has occurred.
Lamivudine (3TC)	Oral solution: 10 mg/ml Tablets: 150 mg; FDC tablets: ABC/3TC 120/60 mg; ABC/3TC 600/300 mg, TLD 300/300/50 mg ABC/3TC/DTG 600/300/50 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg		Well tolerated, adverse-effects uncommon. Pure red cell aplasia causing anaemia can occur but is very rare.
Zidovudine (AZT)	Oral solution: 10 mg/ml Tablets: 100 mg, 300 mg Capsules: 100 mg FDC tablet: AZT/3TC 300/150 mg	Tablets and FDC: **YES** Capsules: Can be opened and added to a small amount of soft food/liquid and ingest immediately.	Avoid or use with caution in neonates or children with anaemia (Hb <8 g/dl) due to potential to cause bone marrow suppression.
Tenofovir (TDF)	Tablets: 300 mg FDC tablets: TDF/FTC 300/200 mg, TEE 300/200/600 mg, TLD 300/300/50 mg	Tablet and FDC tablets: **YES**	TDF may be prescribed for adolescents ≥ 10 years of age AND ≥ 30 kg body weight after ensuring adequate renal function by checking eGFR/creatinine using the appropriate formula (refer to HIV guidelines). TDF is usually prescribed as part of an FDC tablet: TDF/FTC, TDF/FTC/EFV or TDF/3TC/DTG. To assess for TDF-induced nephrotoxicity, do creatinine and eGFR at months 3 and 10 and thereafter repeat every 12 months.
Lopinavir/ ritonavir (LPV/r)	Oral solution: 80/20 mg/ml Capsules: Pellets 40/10 mg per capsule Tablets: 200/50 mg, 100/25 mg FDC capsules: ABC/3TC/LPV/r 30/15/40/10 mg	Tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.** Capsules: Can be opened and added to a small amount of soft food/liquid and ingest immediately.	Oral solution should be refrigerated/stored at room temperature (if <25°C) for up to 6 weeks. Preferably administer oral solution with food as increases absorption. Strategies to improve tolerance and palatability of oral solution: coat mouth with peanut butter, dull taste buds with ice, follow dose with sweet foods. Many drug-drug interactions.# LPV/r 40/10 mg capsules should be opened, and contents (pellets) of each capsule poured onto a spoon of soft food and fed to child. Don't try and dissolve pellets in food or water as they will develop a bad taste. ABC/3TC/LPV/r capsules should be opened and contents (granules) of each capsule poured onto a spoon of soft food or dissolved in water and fed to child. Capsules should never be swallowed whole. Discard capsule casing after contents have been emptied from it.
Ritonavir (RTV)	Oral powder: 100 mg/packet Tablets: 100 mg		Each 100 mg packet of RTV powder should be mixed with a small amount of water or soft food and immediately ingested. Many drug-drug interactions.#
Atazanavir (ATV)	Capsules: 150 mg, 200 mg FDC tablets: ATV/RTV 300/100 mg	Capsules: Can be opened and added to a small amount of soft/food/liquid and ingested immediately. FDC tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.**	ATV is used in combination with RTV. May cause unconjugated hyperbilirubinaemia resulting in jaundice but this does not indicate hepatic toxicity and not a reason to discontinue the drug unless it is worrying the patient. Consider drug-drug interactions.#
Dolutegravir (DTG)	Dispersible tablet (DT): 10 mg Film coated (FC) tablets: 50 mg FDC tablets: TLD 300/300/50 mg FDC tablets: ABC/3TC/DTG 600/300/50 mg	Dispersible tablets: **YES** Film coated tablets (including FDCs): **YES**	Iron supplements decrease DTG concentrations if taken together on an empty stomach. To prevent this, DTG and iron supplements can be taken at the same time if taken with food. May be helpful to administer as a morning dose rather than an evening dose if insomnia occurs with evening dosing. May raise creatinine levels by up to 15% without affecting renal function. Consider drug-drug interactions. # DTG DT and DTG FC tablets are not bioequivalent; 30 mg of DTG DT corresponds to 50 mg DTG FC tablets. DTG 50 mg FC tablets are preferred for children who have reached 20 kg (unless they cannot swallow tablets).
Efavirenz (EFV)	Capsules: 50 mg, 200 mg Tablets: 50 mg, 200 mg, 600 mg FDC tablets: TEE 300/200/600 mg	Tablets: **NO** **Must be swallowed whole and not divided, crushed or chewed.** Capsules: **YES**. Open and add to small amount of soft food and ingest immediately	Best given at bedtime to reduce CNS side-effects, especially during first 2 weeks. Consider drug-drug interactions.#

FDC = fixed dose combination;
eGFR = estimated glomerular filtration rate;
GIT = gastrointestinal tract;
TEE = Tenofovir/Emtricitabine/Efavirenz;
TLD = Tenofovir/Lamivudine/Dolutegravir;

Annexure 6 *Antiretroviral Drug Dosing Chart for Children (2022)*

Compiled by Child and Adolescent Committee of SA HIV Clinicians Society in collaboration with the Department of Health

	Abacavir + Lamivudine (ABC + 3TC)	**Dolutegravir (DTG)**	**Dolutegravir when on Rifampicin**	**Abacavir (ABC)**	**Lamivudine (3TC)**	**Zidovudine (AZT)**
Target dose	As for individual medicines **ONCE daily**	By weight band **ONCE daily**	By weight band **TWICE DAILY**	8 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 16 mg/kg/dose **ONCE daily**	4 mg/kg/dose **TWICE daily** OR **If ≥ 10 kg:** 8 mg/kg/dose **ONCE daily**	180 - 240 mg/m^2/dose **TWICE daily**
Available formulations	Dispersible tablet FDC: ABC/3TC 120/60 mg Tablets FDC: ABC/3TC 600/300 mg ABC/3TC/DTG 600/300/50 mg	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg **DT AND FC TABLETS ARE NOT BIOEQUIVALENT**	Dispersible tabs (DT) 10 mg, Film coated (FC) tabs 50 mg, FDC: TLD 300/300/50 mg OR ABC/3TC/DTG 600/300/50 mg **DT AND FC TABLETS ARE NOT BIOEQUIVALENT**	Sol. 20 mg/ml Tabs 60 mg (scored, dispersible), 300 mg (not scored)	Sol. 10 mg/ml Tabs 150 mg (scored)	Sol. 10 mg/ml Tabs 100 mg, 300 mg (not scored), FDC: AZT/3TC 300/150 mg
Wt. (kg)	Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg					
3 - 5.9	1 x 120/60 mg tab od	0.5 x 10 mg DT od	0.5 x 10 mg DT bd	3 ml bd **OR** 1 x 60 mg tab bd	3 ml bd	6 ml bd
6 - 9.9	1.5 x 120/60 mg tabs od	1.5 x 10 mg DT od	1.5 x 10 mg DT bd	4 ml bd **OR** 1.5 x 60 mg tab bd	4 ml bd	9 ml bd
10 - 13.9	2 x 120/60 mg tabs od	2 x 10 mg DT od	2 x 10 mg DT bd	**Once daily dosing > 10 kg**	**Once daily dosing > 10 kg**	12 ml bd **OR** 1 x 100 mg tabs bd
				4 x 60 mg tabs od **OR** 12 ml od	12 ml od	
14 - 19.9	2.5 x 120/60 mg tabs od	2.5 x 10 mg DT od	2.5 x 10 mg DT bd	5 x 60 mg tabs od **OR** 1 x 300 mg tab od	1 x 150 mg tab od	2 x 100 mg tabs am + 1 x 100 mg tab pm **OR** 15 ml bd
20 - 24.9	3 x 120/60 mg tabs od	3 x 10 mg DT od **OR** 1 x 50 mg FC tab od	3 x 10 mg DT bd **OR** 1 x 50 mg FC tab bd	1 x 300 mg tab + 1 x 60 mg tab od **OR** 6 x 60 mg tabs od	2 x 150 mg tabs od	2 x 100 mg tabs bd **OR** 20 ml bd
25 - 29.9	1 x 600/300 mg tab od **OR** ABC/3TC/DTG FDC (600/300/50 mg) if eligible od	1 x 50 mg FC tab od **OR** FDC: ABC/3TC/DTG if eligible od	1 x 50 mg FC tab bd OR FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later	2 x 300 mg tabs od		1 x 300 mg tab bd **OR** 1 x AZT/3TC 300/150 mg tab bd
30 - 39.9		1 x 50 mg FC tab od **OR** FDC: TLD if eligible od **OR** FDC: ABC/3TC/DTG if eligible od	1 x 50 mg FC tab bd **OR** FDC: TLD if eligible od + 50 mg DTG FC tab 12 hours later **OR** FDC: ABC/3TC/ DTG if eligible od + 50 mg DTG FC tab 12 hours later			
≥ 40						

* Avoid LPV/r solution in any full-term infant <14 days of age and any premature infant <42 weeks post conceptual age (corrected gestational age) or obtain expert advice.

✦ Children weighing 25-29.9 kg may also be dosed with LPV/r 200/50 mg adult tabs: 2 tabs am + 1 tab pm.

Atazanavir + ritonavir should not be used in children/adolescents on treatment with Rifampicin, obtain expert advice.

No dosage adjustments are required for children receiving treatment with Efavirenz and Rifampicin.

od = once a day;
nocte = at night;
bd = twice a day;
am = in the morning;
pm = in the evening;
std = standard;

Lopinavir / ritonavir (LPV/r)	Abacavir + Lamivudine + Lopinavir/ ritonavir	Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin)		# Atazanavir (ATV) + Ritonavir (RTV)	Efavirenz (EFV)	
300/75 mg/m²/dose LPV/r **TWICE daily**	**By weight band TWICE daily**	LPV/r std dose + super-boosting with ritonavir (RTV) powder **TWICE daily** (≥ 0,75 x LPV dose bd)	Double-dose LPV/r tabs ONLY if able to swallow whole LPV/r tabs **TWICE daily**	By weight band **ONCE daily**	By weight band **ONCE daily**	**Target dose**
Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paed tabs 100/25 mg **TABLETS MUST BE SWALLOWED WHOLE** Pellets 40/10 mg per capsule **ONLY FOR USE IF NOT TOLERATING LPV/r SOLUTION. CAPSULES ARE NOT RECOMMENDED < 6 MONTHS OF AGE**	Caps 30/15/40/10 mg **IF PATIENT IS ON RIFAMPICIN TB TREATMENT, ADD RTV POWDER** (next column)	Oral powder 100 mg/packet	Adult tabs 200/50 mg, **Paed tabs** 100/25 mg	ATV caps 150, 200 mg; RTV tabs 100 mg; FDC: ATV/RTV 300/100 mg RTV TABLETS AND ATV/r FDC TABLETS MUST BE SWALLOWED WHOLE	Caps/tabs 50, 200, 600 mg; FDC: TEE 300/200/600 mg; TABLETS MUST BE SWALLOWED WHOLE	**Available formulations**
Consult with a clinician experienced in paediatric ARV prescribing for neonates (< 28 days of age) and infants weighing < 3kg						**Wt. (kg)**
* 1 ml bd **OR** 2 capsules bd	2 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 100 mg (1 packet) bd	Do not use double-dose LPV/r tabs	Not recommended	Not recommended	**3 - 5.9**
* 1.5 ml bd **OR** 3 capsules bd	3 capsules bd					**6 - 9.9**
2 ml bd OR 4 capsules bd **OR** 2 x 100/25 mg paed tabs am + 1 x 100/25 mg paed tab pm	4 capsules bd	LPV/r std dose (see purple column) + oral RTV powder 200 mg (2 packets) bd	3 x 100/25 mg **paed tabs** bd	ATV 1 x 200 mg cap od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	1 x 200 mg cap/tab nocte	**10 - 13.9**
2.5 ml bd OR 5 capsules bd **OR** 2 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd	5 capsules bd		4 x 100/25 mg **paed tabs** bd **OR** 2 x 200/50 mg **adult tabs** bd		1 x 200 mg cap/tab + 2 x 50 mg caps/ tabs nocte	**14 - 19.9**
3 ml bd OR 6 capsules bd **OR** 2 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd	6 capsules bd					**20 - 24.9**
3.5 ml bd OR 7 capsules bd **OR** 3 x 100/25 mg paed tabs bd **OR** 1 x 200/50 mg adult tab bd + 1 x 100/25 mg paed tab bd	Not recommended	LPV/r std dose (see purple column) + oral RTV powder 300 mg (3 packets) bd	6 x 100/25 mg **paed tabs** bd **OR** 3 x 200/50 mg **adult tabs** bd	1 x ATV/RTV 300/100mg FDC od **OR** ATV 2 x 150 mg caps od + RTV 1 x 100 mg tab or 100 mg oral powder (1 packet) od	2 x 200 mg caps/ tabs nocte	**25 - 29.9**
5 ml bd OR 10 capsules bd **OR** 4x100/25 mg paed tabs bd **OR** 2x200/50 mg adult tabs b			8 x 100/25 mg **paed tabs** bd **OR** 4 x 200/50 mg **adult tabs** bd			**30 - 39.9**
					2 x 200 mg caps/ tabs nocte **OR** FDC: TEE if eligible od	**≥ 40**

FC = film coated
DT = dispersible tablet
FDC = fixed dose combination;
TLD = tenofovir/lamivudine/dolutegravir;
TEE = tenofovir/emtricitabine/efavir

Weight (kg)	3 - 5.9	6 - 13.9	14 - 24.9	≥ 25
Cotrimoxazole Dose	2.5 ml od	5 ml or ½ tab od	10 ml or 1 tab od	2 tabs od
Multivitamin Dose	2.5 ml od	2.5 ml od	5 ml od	10 ml od

- Disclosure should ideally be a gradual process over many years, advancing from partial disclosure to full disclosure, post-disclosure, and ongoing support.
- Ideally full disclosure should take place between 10 and 14 years old if the child is of normal cognition and maturity, making sure that it is done before sexual debut.
- The parent or caregiver (PCG) should be prepared for disclosure and supported through each step by the healthcare worker (HCW). PCGs should decide what role the HCW should play.
- The HCW/PCG should make sure to use age-appropriate language, pictures where possible, excellent counselling skills, be aware of emotions, use a private space, and refer to psychologists and social workers when necessary.

Failure of full disclosure by early teenage years can lead to:

- Poor adherence
- Emotional difficulties
- Poor school performance
- HIV transmission if sexually active
- The adolescent finding out their HIV status through other mechanisms
- Psychological issues if disclosure is not sensitively done

No disclosure yet (0 — 4 Years)

- Conduct the consultation with the child present (but do not mention the word HIV if the child can understand the conversation)
- The child is too young for direct information about HIV but explanations to the caregiver about how HIV can affect the child remain important.
- Provide ideas to help the caregiver support the child taking medicine. Congratulate the child on taking their medicines well.
- Address the caregiver's anxieties and inform them that in time you will support them through the partial and full disclosure process as outlined below.
- Provide a safe and welcoming clinic and build a relationship with the child through play/singing.
- Warn the PCG that when the child starts asking questions about why they must take medicine, they should give the information described under partial disclosure below. They should try not to lie and name other illnesses as the reason for needing medication.

Partial Disclosure (5-9 years)

- The child needs to learn about illness and why they must take medicine but not HIV by name yet.
- Introduce the concepts of good and bad health. Talk about how good health can be promoted by eating healthy food, keeping clean, exercising, looking after teeth etc. Explain that medicines help to keep a body healthy and strong.
- Introduce infections as 'germs' that can damage the body/make you sick and (white) blood cells as the part of the body that look for and kill germs.
- Explain that some germs hide, and you need to take medicines to help fight the germs or explain that they were born without enough white blood cells so they need to take medicine every day to make their white blood cells increase so that they can stay healthy and are able to fight the germs
- Advise PCG that they can start teaching their child about HIV and other illnesses without telling them that they have HIV, so that the child learns correct information about HIV and not the negative myths (see the 5 points in the red box below)

Before Full Disclosure:

- Assess the adolescent's cognitive and emotional maturity (if they are passing school at the appropriate level for their age, they can be assumed to be of normal cognitive maturity)
- Prepare the PCG for full disclosure
- Get consent to disclose the adolescent's (and PCG's) HIV status. It is preferable to disclose the PCG's status as well, but not essential if the PCG requests not to.
- Find out what the adolescent knows about HIV already before disclosing to them.
- Educate them about HIV and dispel the negative myths:

Children and adolescents living with HIV (C/ALWH) often learn negative myths about HIV from their community, their friends and school, such as "HIV kills", "people with HIV are promiscuous or bad" and "people with HIV can't live a normal life". It is therefore extremely important to educate C/ALWH and dispel all of these myths before you tell them they have HIV. Different ways of educating them include teaching them about a few different illnesses, holding education sessions in the clinic or telling their parents to teach them about HIV at home from a young age. Five important things for them to understand include:

1. These days we have very good treatment for HIV, so people living with HIV (PLHIV) can remain perfectly healthy and never get AIDS.
2. PLHIV can live as long as people without HIV if they take their treatment every day.
3. Anyone can have HIV and it does not make them different/bad. Many people around you have HIV and you do not know because they are just as healthy as those without HIV.
4. PLHIV can have relationships and have children, and if they are taking their treatment and have a suppressed viral load, they will not transmit HIV to their sexual partner or children.
5. Living with HIV does not prevent people from living a completely normal life and following any career they want.

Full disclosure:
Ensure they first understand points 1- 5 in the box above before you explain that:

- They were born with a germ/virus called HIV, which can kill their white blood cells so they can't protect their body from other germs.
- The medicine they receive works very well at making the HIV virus sleep so that it can't kill white blood cells. That way the body is well protected from other germs and you won't get sick.
- If you don't take your medicines every day the HIV virus can get stronger and prevent the medicines from working
- They need to understand their responsibility for not transmitting HIV e.g. safer sex, and family planning

Once the adolescent has been disclosed to it is very important to offer for them to join a support club, answer any questions they have, let them express their emotions, and make sure they understand the following things:

- Repeat the 5 points mentioned in the red box above, now relating to the adolescent themselves.
- It is not their mother's fault that the adolescent got HIV. When their mother was pregnant we did not have such good medicine, so many babies got HIV from their mothers, but nowadays we have very good medicine so if an adolescent wants to have a baby one day the medicine will be able to prevent their baby from getting HIV.
- It is not their parents' fault they have HIV: millions and millions of people in the world have HIV and they did nothing wrong and they are no different to anyone else. You can't tell who has HIV by looking at them because they will be healthy when they are taking their medication.
- They are allowed to keep their HIV status a secret, and are allowed to lie about it if their friends or strangers ask, because some people don't know enough about HIV and might treat them differently or think that it means they are going to be very sick. It is up to them and their PCG to decide who they think deserves to know.
- When they are ready to have a boyfriend/girlfriend or become sexually active they can come to the clinic to discuss how or when they would like to tell their partner about their HIV status.
- They should know how much their PCG loves them and be grateful for all the effort they put in over the years to make sure that they took their treatment every day to keep them healthy. This is a good opportunity for the child to thank the PCG and for them to tell each other how much they love them and give each other a hug.
- They must feel free to come into the clinic any time to ask any questions they have or discuss anything they are struggling with.

Post Disclosure (10-19 years)

- During follow up visits after full disclosure the information mentioned under "Full Disclosure" will need to be repeat many times as the C/ALHIV will not remember everything, might be in denial, might have since heard conflicting information, and will develop a deeper understanding of the information as they get older.
- They must feel free to ask any questions they might have.
- It is very important to assess their mental health and how they are coping with the information and with adolescence in general.
- Discuss whether they have or would like to disclose their status to friends or partners.
- Ask (privately) if they are sexually active or are thinking of becoming sexually active. Educate about safe sex, condom use, and family planning.
- Repeat information about the importance of taking medication every day to stay healthy and avoid development of drug-resistant HIV.

For more details on disclosure, please refer to the
Differentiated Care Models Standard Operating Procedures 2023 SOP 3: Child and Adolescent Disclosure Counselling
or contact the Right to Care Helpline on 082 352 6642

Other Resources and Important Information

Adverse Drug Reactions

Surveillance of all adverse drug reactions (ADRs) is fundamental. Healthcare professionals and consumers are urged to report any ADRs, adverse events following immunisation (AEFI), and product quality concerns to the SAHPRA pharmacovigilance office using one of the following reporting methods:

1. Form requests and submissions via e-mail: adr@sahpra.org.za (For the ***ADR reporting form, see page 39***)
2. Online e-reporting portal: https://primaryreporting.who-umc.org/ZA
3. Med Safety smartphone application: search for "Medsafety" on apple store or google play store and install the app on your mobile device. Select South Africa and you are ready to go. Information on the Med Safety App: https://medsafety.sahpra.org.za/

More information available from:
- The SAHPRA pharmacovigilance office - Tel: 012 501 0311
- SAHPRA's Health Products Vigilance link: https://www.sahpra.org.za/health-products-vigilance/
- Information on AEFIs, including COVID-19 vaccines: https://aefi-reporting.sahpra.org.za/

Drug Stock-outs

To report drug stock-outs, or for assistance with drug stock-outs, please contact Stop Stockouts:
SMS/please call me/WhatsApp (084) 855-7867
Email: reports@stockouts.org

Resources for Clinical Management and Drug Interactions

National HIV & TB Health Care Worker Hotline: 0800 212506
Email pha-mic@uct.ac.za
SMS/please call me/WhatsApp (071) 840-1572

Right to Care Paediatric, Adolescent and Adult HIV Helpline (082) 352-6642
Right to Care Helpline can be contacted vial call/SMS/please call me/WhatsApp/missed call

KZN Paediatric Hotline: 0800 006 603

ADR Reporting Form

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NDoH Pharmacovigilance Centre for Public Health Programmes (NPC)
Adverse Drug Reaction (ADR) / Product Quality Problem Report Form
This report will be shared with the
South African Health Products Authority (SAHPRA)
adr@sahpra.org.za or call 012501031

Reporting Health Care Facility/Practice				
Tel: 012 395 9506 (NPC) **Fax:** 086 241 2473 **Email:** npc@health.gov.za	Facility/Practice			
	District		Tel	
	Province		Fax	

Patient Details									
Patient Initials		File/Reference Number			Date of Birth/Age				
Sex	□M □F □Unk	Race		Weight (kg)		Height (cm)		Pregnant?	□N □Y
Allergies				Estimated Gestational Age at time of reaction					

Suspect Medicine(s) **[Medicines suspected to have caused the ADR]**

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

All other Medicines Patient was taking at time of reaction **[Including over-the-counter and herbal products]**

Trade Name [Generic Name if Trade Name is unknown]	Name of Manufacturer	Route	Dose (mg) and Interval	Date Started	Date Stopped	Reason for use	Batch Number / Expiry Date

Adverse Drug Reaction/Product Quality Problem			
Date and time of onset of reaction		Date reaction resolved/duration	

Please describe Adverse Reaction/Product Quality Problem: (kindly add as much clinical information as possible)

Intervention **[tick all that apply]**	**Patient Outcomes** **[tick all that apply]**
□ No intervention	□ Patient recovered □ Patient recovering
□ Intervention unknown	□ Patient not recovering □ Outcome unknown
□ Patient counselled/non-medical treatment	□ Patient died; Date of death:_____
□ Discontinued Suspect Drug; **Replaced with**:_____	□ Impairment/Disability □ Congenital Anomaly
□ Decreased Suspect Drug Dosage; **New Dose**:_____	□ Patient hospitalised or hospitalisation prolonged
□ Treated ADR with:_____	□ Life threatening □ Other:_____
□ Referred to hospital; **Hospital Name**_____	□ ADR reappeared after restarting suspect drug/similar drug (rechallenge)?: □ N □ Y □ Not done □ Unknown
□ Other Intervention (e.g. dialysis): _____	

Laboratory Results

Lab Test	Test Result	Test Date	Lab Test	Test Result	Test Date

Co-morbidities/Other Medical Condition(s) **[tick all that apply]**

□ Hypertension □ Diabetes □ Asthma □ Tuberculosis □ HIV/AIDS □ Other:

Reported by

Name		E-mail	
Designation	□ Nurse □ Pharmacist □ Doctor □ Other:	Date Reported	
Telephone	Signature	**VERSION 35.0 May 2021**	

THIS ADR REPORT IS NOT A CONFIRMATION THAT THE REPORTER OR THE SUSPECT MEDICINE(S) CAUSED THE ADR

Abbreviations

3TC	Lamivudine
ABC	Abacavir
AGL	Adherence Guideline
AHD	Advanced HIV disease
ALT	Alanine transaminase
am	In the morning
ANC	Antenatal Care
APC	Adult Primary Care
ART	Antiretroviral therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
bd	Twice daily
BMI	Body mass index
CM	Cryptococcal meningitis
CNS	Central nervous system
CPT	Cotrimoxazole preventive therapy
CrAg	Cryptococcal Antigen
CVS	Cardiovascular
DILI	Drug-induced liver injury
DMOC	Differentiated Models of Care
DR	Drug-resistant
DS	Drug-sensitive
DT	Dispersible tablet
DTG	Dolutegravir
EAC	Enhanced Adherence Counselling
eGFR	Estimated glomerular filtration rate
EFV	Efavirenz
EX-PUP	External pick-up point
FAC-PUP	Facility pick-up point
FC	Film coated
FDC	Fixed-dose combination
GIT	Gastrointestinal tract;
Hb	Haemoglobin
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
InSTI	Integrase strand transfer inhibitor
IRIS	Immune reconstitution inflammatory syndrome
IUCD	Intrauterine contraceptive device
LP	Lumbar puncture
LPV/r	Lopinavir/ritonavir
MMD	Multi-month Dispensing
MUAC	Mid-upper arm circumference
NA	Not applicable
NCDs	Non-communicable diseases
nocte	at night
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NTDs	Neural tube defects
NVP	Nevirapine
od	Once daily
OI	Opportunistic infection
PBFW	Pregnant and breastfeeding women
PCR	Polymerase chain reaction test for HIV
PHC EML	Primary Health Care Essential Medicines List
PI	Protease inhibitor
PJP	Pneumocyctis jerovecii pneumonia
PLHIV	People living with HIV
pm	in the evening
RPCs	Repeat prescription collection strategies
RT	Resistance test
sCR	Serum creatinine

std	Standard
STIs	Sexually transmitted infections
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
TEE	Tenofovir + emtricitabine + efavirenz
TLD	Tenofovir + lamivudine + dolutegravir
TPT	TB preventive treatment
VL	Viral load
VT	Vertical transmission
WHO	World Health Organisation

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SUPPORTING ORGANISATION

World Health Organisation
Right to Care
International AIDS Society
CDC
ANOVA
Medicines Information Centre

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