

REPOSITORY OF PROFESSIONAL INFORMATION AND PATIENT INFORMATION LEAFLETS

Latest publication date	28/06/2019
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The South African Health Products Regulatory Authority (SAHPRA) has a mandate to make information related to the safe and efficacious use of medicines available to the public. The Medicines and Related Substances Act (101 of 1965), as amended, states the following:

“22B Publication of information relating to medicines, scheduled substances, medical devices or IVDs

(1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, scheduled substance, medical device or IVD.

(2) The Director-General may publish the information referred to in subsection (1) or release it to the public in a manner which he or she thinks fit.”

In keeping with the above, SAHPRA is publishing Professional Information (PI) and Patient Information Leaflets (PILs) for South African products through the central repository contained herein. This repository is intended to benefit all of SAHPRA’s stakeholders, particularly aiding the informed clinical treatment of South African patients.

The repository is presented in the table on the following page, arranged alphabetically by Active Pharmaceutical Ingredients (APIs). The latest SAHPRA-approved PI/PILs are accessible via the hyperlinks.

Note that in the interest of time, all of the PI/PILs published to date are still in their current, MCC format. SAHPRA has prioritised selected innovator products associated with resubmission window 1 (HIV, TB, Hepatitis and Vaccines) for format updates. Once these (or any other future) variation applications are finalised, the updated PI/PILs will replace those currently published on the website.

LIST OF ABBREVIATIONS

Abbreviation / terminology	Explanation
API	Active Pharmaceutical Ingredient
HCR	Holder of Certificate of Registration
IVD	In vitro diagnostic medical device
PI	Professional Information
PIL	Patient Information Leaflet
SAHPRA	South African Health Products Regulatory Authority

SAHPRA repository of Professional Information and Patient Information Leaflets

API(s)	Product name	HCR	Dosage form(s)	Strength(s)	PI	PIL	Approval date
Atazanavir	Reyataz	Equity Pharmaceuticals	Capsule	150mg, 200mg	Link	Link	25/11/2016
Dolutegravir, Abacavir, Lamivudine	Trelavue	GSK	Tablet	50mg, 600mg, 300mg	Link	Link	21/04/2016
Dolutegravir, Lamivudine, Tenofovir disoproxil fumarate	Volutrip	Aurobindo	Tablet	50mg, 300mg, 300mg	Link	Link	31/08/2018
Ethionamide	Ethionamide Macleods 250mg	Macleods Pharmaceuticals	Tablet	250mg	Link	Link	25/11/2016
Lamivudine, Tenofovir disoproxil fumarate	Mivuten	Cipla	Tablet	300mg, 300mg	Link	Link	08/04/2019
Rifampicin, Isoniazid	Rimactazid Paed 60/60	Sandoz	Tablet	60mg, 60mg	Link	Link	01/10/2018
Rifampicin, Isoniazid	Rimactazid Paed 150/75	Sandoz	Tablet	150mg, 75mg	Link	NA	01/10/2018
Rifampicin, Isoniazid, Pyrazinamide	Co-Afaris Paed 75/50/150	Macleods Pharmaceuticals	Tablet	75mg, 50mg, 150mg	Link	Link	26/10/2018
Rifampicin, Isoniazid, Pyrazinamide, Ethambutol HCl	Rifafour e-275	Sanofi-Aventis	Tablet	150mg, 75mg, 400mg, 275mg	Link	Link	12/04/2018
Tenofovir disoproxil fumarate, Lamivudine, Efavirenz	Eflaten	Mylan	Tablet	300mg, 300mg, 600mg	Link	Link	06/07/2016
Zidovudine	Retrovir IV	GSK	Infusion	200mg / 20ml	Link	Link	29/06/2018

PRODUCTS PENDING PUBLICATION

The table below provides transparency on the products which SAHPRA is in the process of adding to the central repository. This list is currently restricted to products associated with the first resubmission window of the Backlog Clearance Program. The publication of PI/PILs will soon extend to the remaining resubmission windows once announced to SAHPRA's industry partners.

APIs	Product name	HCR
Abacavir, Lamivudine	Kivexa	GSK
Dolutegravir	Tivicay	GSK
Lamivudine	3 TC	GSK
Abacavir	Ziagen	GSK
Lopinavir, Ritonavir	Aluvia	AbbVie
Ritonavir	Norvir	AbbVie
Zidovudine	Cipla Zidovudine	Cipla
Dolutegravir, Lamivudine, Tenofovir	Telado	Cipla
Darunavir	Prezista	Aspen Pharmacare
Emtricitabine, Tenofovir	Truvada	Aspen Pharmacare
Tenofovir	Viread	Aspen Pharmacare
Capreomycin sulphate	Capastat	Aspen Pharmacare
Isoniazid	Lennon Isoniazid	Aspen Pharmacare
Tenofovir, Emtricitabine, Efavirenz	Atripla	MSD

QUERIES

Please direct any queries regarding this PI/PIL repository to backlog@sahpra.org.za, including the text "[PI/PIL repository]" in the start of the subject line.