



FDA ADVISORY
No. **2021-0103**

21 JAN 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC



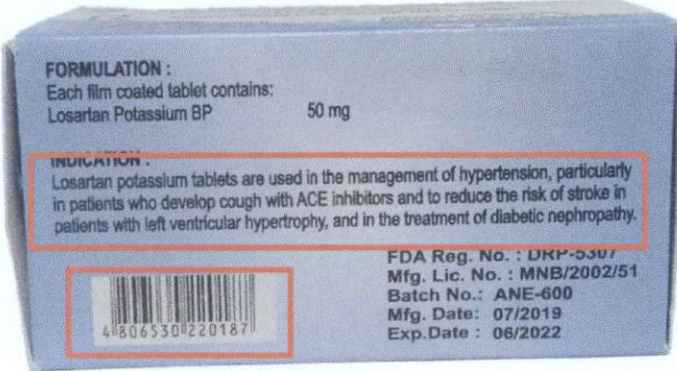
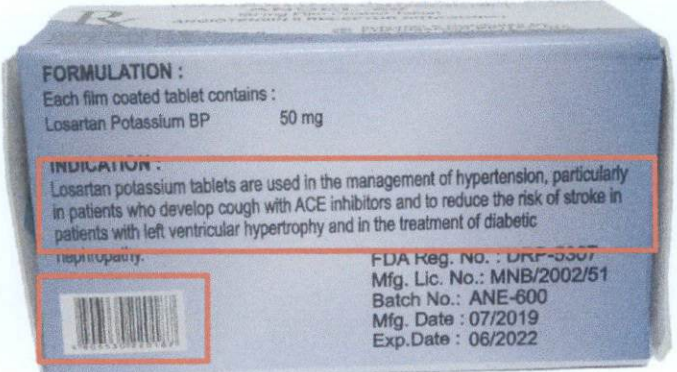
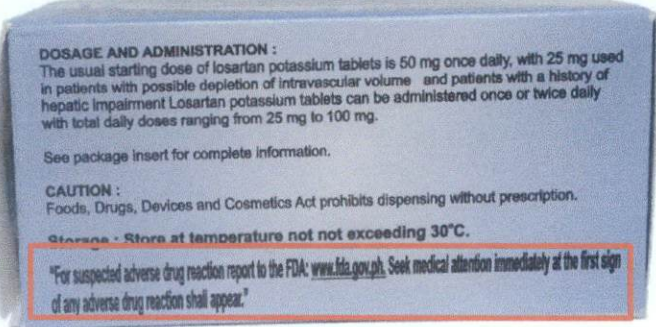
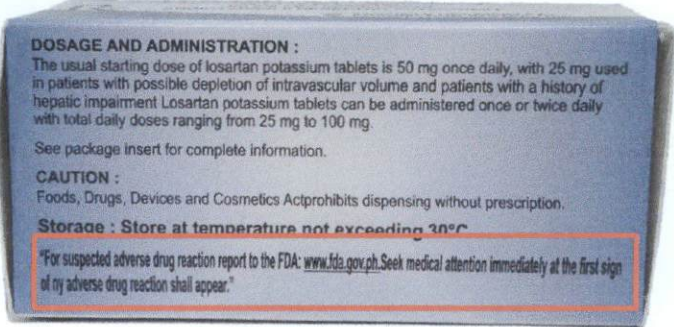
SUBJECT: Public Health Warning Against the Purchase and Use of the Verified Counterfeit Losartan Potassium (Angel-50) 50mg Film Coated Tablet

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit Losartan Potassium (Angel-50) 50mg Film Coated Tablet:

AUTHENTIC	COUNTERFEIT
<p>Note: The blister packaging of the counterfeit version has different pantone color and fonts than that of authentic drug product.</p>	

Figure 1. Comparison between the Authentic and Verified Counterfeit Losartan Potassium (Angel-50) 50mg Film Coated Tablet



AUTHENTIC	COUNTERFEIT
 <p>100 Tablets</p> <p>LOSARTAN POTASSIUM ANGEL-50 50 mg Film Coated Tablet ANGIOTENSIN II RECEPTOR ANTAGONIST</p> <p>Manufactured By : HEALER'S LAB, UNIT II Plot No. 33, HPSIDC, Extn. Baddi, Distt. Solan (HP), INDIA</p> <p>Imported & Distributed By : PHARMAKON BIOTEC INC. Unit G-01, Cityland 8, 98 Sen. Gil Puyat Ave., Makati City, Philippines.</p>	 <p>100 Tablets</p> <p>LOSARTAN POTASSIUM ANGEL-50 50 mg Film Coated Tablet ANGIOTENSIN II RECEPTOR ANTAGONIST</p> <p>Manufactured By : HEALER'S LAB, UNIT II Plot No. 33, HPSIDC, Extn. Baddi, Distt. Solan (HP), INDIA</p> <p>Imported & Distributed By : PHARMAKON BIOTEC INC. Unit G-01, Cityland 8, 98 Sen. Gil Puyat Ave., Makati City, Philippines.</p>
 <p>FORMULATION : Each film coated tablet contains: Losartan Potassium BP 50 mg</p> <p>INDICATION : Losartan potassium tablets are used in the management of hypertension, particularly in patients who develop cough with ACE inhibitors and to reduce the risk of stroke in patients with left ventricular hypertrophy, and in the treatment of diabetic nephropathy.</p> <p>FDA Reg. No. : DKP-5307 Mfg. Lic. No. : MNB/2002/51 Batch No. : ANE-600 Mfg. Date : 07/2019 Exp. Date : 06/2022</p> <p>4 806530 220187</p>	 <p>FORMULATION : Each film coated tablet contains : Losartan Potassium BP 50 mg</p> <p>INDICATION : Losartan potassium tablets are used in the management of hypertension, particularly in patients who develop cough with ACE inhibitors and to reduce the risk of stroke in patients with left ventricular hypertrophy and in the treatment of diabetic nephropathy.</p> <p>FDA Reg. No. : DRP-5307 Mfg. Lic. No. : MNB/2002/51 Batch No. : ANE-600 Mfg. Date : 07/2019 Exp. Date : 06/2022</p>
 <p>DOSAGE AND ADMINISTRATION : The usual starting dose of losartan potassium tablets is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume and patients with a history of hepatic impairment Losartan potassium tablets can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg.</p> <p>See package insert for complete information.</p> <p>CAUTION : Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>Storage : Store at temperature not exceeding 30°C.</p> <p>"For suspected adverse drug reaction report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction shall appear."</p>	 <p>DOSAGE AND ADMINISTRATION : The usual starting dose of losartan potassium tablets is 50 mg once daily, with 25 mg used in patients with possible depletion of intravascular volume and patients with a history of hepatic impairment Losartan potassium tablets can be administered once or twice daily with total daily doses ranging from 25 mg to 100 mg.</p> <p>See package insert for complete information.</p> <p>CAUTION : Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.</p> <p>Storage : Store at temperature not exceeding 30°C</p> <p>"For suspected adverse drug reaction report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction shall appear."</p>

Note: Wrong spelling of "Philippines"

Note:

- Different size of the indication
- Barcode size is different

Note: Adverse Drug Reaction statement boldness is different.

Figure 2. Comparison between the Authentic and Verified Counterfeit Losartan Potassium (Angel-50) 50mg Film Coated Tablet

The FDA together with the Marketing Authorization Holder (MAH), Pharmakon Biotec Inc., have verified that the sample drug product is counterfeit.

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. The importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009, and Republic Act No. 8203 or the Special Law on Counterfeit Drugs. Anyone found selling the said counterfeit drug product will be penalized.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of counterfeit health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Director General

DTN: 

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