



FDA ADVISORY
No. 2022-1520

02 AUG 2022

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Ivermectin (Ivercureme) 15 mg 10 Capsules"

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered drug product:

Each capsule contains
Ivermectin _____ 15mg
Excipient: Dextrose Anhydrous (q.s.)

DOSAGE AND ADMINISTRATION:
For Prophylaxis: 1 capsule every 2 weeks
For Treatment: 1 capsule per day for 5-7 days
or as prescribed by a physician

STORAGE CONDITION:
Store at temperature not exceeding 30°C.
Protect from heat and moisture.
Keep out of reach of children

Not to be used in children who weight below 15kg or during pregnancy or breast feeding and also persons with liver cirrhosis and meningitis
Caution: Foods, Drug, Devices and Cosmetics. Acts prohibits dispensing without prescription

Mfg Date: 04/2021
Exp Date: 04/2023

IVERMECTIN (15mg capsule)

Indication:
Ivermectin (15mg)
Excipient: Dextrose Anhydrous (q.s.)

Contraindications:
Hypersensitivity to ivermectin or any of its ingredients.

Warnings:
This drug is not for oral use. It is a potent anthelmintic and should be used only for the treatment of parasitic infections.

Precautions:
This drug is not for oral use. It is a potent anthelmintic and should be used only for the treatment of parasitic infections.

Adverse Effects:
Headache, dizziness, nausea, vomiting, diarrhea, abdominal pain, and allergic reactions.

Drug Interactions:
None known.

How to Use:
Take one (1) 15mg capsule or 10 mg capsule for 5-7 days as directed by the doctor.

How to Store:
Store at room temperature (20°C to 25°C).

How to Handle:
Avoid contact with the drug product. Do not touch the capsules. Wash hands after handling.

Other Information:
Keep out of reach of children. Do not use if the seal is broken. Do not use if the capsules are discolored or contain any liquid.

Ivermectin (Ivercureme) 15 mg 10 Capsules
Trader: Ivercureme, USA

Figure 1: Unregistered drug product



FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug product has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal** feature accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this 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 unregistered health products, kindly e-mail us via ereport@fda.gov.ph. 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.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN: 

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