



FDA ADVISORY
No. **2023-0131**

17 JAN 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Veterinary Drug Products:

- 1. PaWell Veterinarian's Choice Gentamicin Sulfate 5mg/ml Sterile Ophthalmic Solution (Drops) 15 ml**
- 2. PaWell Veterinarian's Choice Bromhexine with oregano 4 mg/mL Suspension 60mL [Vanilla Flavor]**

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

PAWELL
Veterinarian's Choice

GENTAMICIN SULFATE

5mg/ml
Sterile Ophthalmic Solution (Drops)

ANTIBACTERIAL

Rx

FOR VETERINARY USE ONLY

GENTAMICIN SULFATE
Gentamicin Sulfate Ophthalmic Solution is an aminoglycoside antibiotic, which inhibits the growth of bacteria that cause infection. It helps to get rid of your pet of those red, itchy and irritated eyes.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C away from direct sunlight. KEEP OUT OF REACH OF CHILDREN.

Exclusively Distributed by:
Pets J Veterinary Products Inc.
Unit E, Ground Floor,
Westgate Tower, Investment Drive
Madriral Park 1, Brgy. Ayala Alabang
Muntinlupa City 1780
Tel no. (02) 8682-2216

FORMULATION:
Gentamicin Sulfate - 5 mg/ml

DOSAGE AND ADMINISTRATION:
Instill one (1) drop into the affected eye(s). In severe infections, dosage may be instructed by the veterinarian.

STORAGE:
Avoid exposure to excessive heat. KEEP OUT OF REACH OF CHILDREN.

Lot No.:
Mfg. Date: September 2022
Exp. Date: September 2023

PaWell Veterinarian's Choice Gentamicin Sulfate 5mg/ml Sterile Ophthalmic Solution (Drops) 15 ml
Distributed by: Pets J Veterinary Products Inc. – Unit E, Ground Floor, Westgate Tower, Investment Drive Madriral Park 1, Brgy. Ayala Alabang Muntinlupa City 1780

Figure 1. Unregistered veterinary drug product





Figure 2. Unregistered veterinary drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products 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 products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if the products are 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 these products are 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.

DTN: 
20230103195833


DR. SAMUEL A. ZACATE
Director General