



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2021-1007**

10 MAY 2021

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Pfizer Atorvastatin Calcium Tablets 20mg [*Label in foreign language*]
2. SY[®] Gentamicin Sulfate Injection – Liusuan Qingdameisu Zhushuye 2ml:8
3. OTC 999[®] Triamcinolone Acetonide Acetate and Miconazole Nitrate and Neomycin Sulfate Cream - Qumixin Rugao [*as reflected in the package insert*]

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



Pfizer Atorvastatin Calcium Tablets 20mg [*Label in foreign language*]
by: Pfizer

Figure 1. Unregistered drug product



硫酸庆大霉素注射液

2ml:8万单位
10支

【成份】硫酸庆大霉素，辅料为无水亚硫酸钠、磷酸。

【性状】本品为无色至微黄色或微黄绿色的澄明液体。

【适应症】1、适用于治疗敏感革兰阴性杆菌，如大肠埃希菌、克雷伯菌属、肠杆菌属、变形杆菌属、沙雷菌属、铜绿假单胞菌以及葡萄球菌甲氧西林敏感株所致的严重感染，如败血症、下呼吸道感染、肠道感染、盆腔感染、腹腔感染、皮肤软组织感染、复杂性尿路感染等。2、用于敏感细菌所致中枢神经系统感染，如脑膜炎、脑室炎时，可同时用本品鞘内注射作为辅助治疗。详见说明书。

【用法用量】详见说明书。

【不良反应】【禁忌】【注意事项】等详见说明书。

【规格】2ml:8万单位

【贮藏】密封，在凉暗处保存。

【包装】每盒10支。

【批准文号】国药准字 H35020363

福建汇天生物药业有限公司
 地址：福建省三明市三元区台江路46号 电话：0598-8337551



SY® Gentamicin Sulfate Injection – Liusuan Qingdameisu Zhusheye 2ml:8

Figure 2. Unregistered drug product





OTC 999® Triamcinolone Acetonide Acetate and Miconazole Nitrate and Neomycin Sulfate Cream - Qumixin Rugao [as reflected in the package insert]

Figure 3. Unregistered 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 its quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

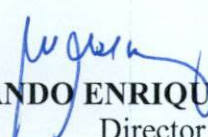
Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

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.

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.


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