



06 APR 2021

FDA ADVISORY
No. **2021-0716**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. OTC 999[®] Ganmaoling Keli [as reflected in the package insert]
2. OTC 999[®] Compound Dexamethasone Acetate Cream – Fufang Cusuandisaimisong Rugao [as reflected in the package insert]
3. OTC Am Ya Feng[®] Quike Compound Paracetamol and Amantadine Hydrochloride Capsules
4. CSPC[®] Amoxicillin Capsules 0.25g [In Foreign Language]
5. Cefradine Capsules 0.25g [In Foreign Language]

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



OTC 999[®] Ganmaoling Keli [as reflected in the package insert]

Figure 1. Unregistered drug product





OTC 999[®] Compound Dexamethasone Acetate Cream
Fufang Cusuandisaimisong Rugao [as reflected in the package insert]

Figure 2. Unregistered drug product



OTC Am Ya Feng[®] Quike Compound Paracetamol And Amantadine Hydrochloride Capsules

Figure 3. Unregistered drug product

石药®
阿莫西林胶囊
AMOXICILLIN CAPSULES

国药准字H13023964

有效期 36 个月
0.25g x 24粒

石药集团
中诺药业(石家庄)有限公司

CSPC® Amoxicillin Capsules 0.25g [In Foreign Language]
by: CSPC

Figure 4. Unregistered drug product

康良®
头孢拉定胶囊
Cefradine Capsules

【用法用量】用法：口服。用量：成人常用量：一次0.25~0.5g(1~2粒)，每6小时1次(一日4次)，感染较严重者一次可增至1g(4粒)，但一日总量不超过4g(16粒)，小儿常用量：按体重一日25~50mg/kg，每6小时1次(一日4次)。

山东鲁抗医药股份有限公司
地址：山东省济宁高新区德源路89号 邮编：272104 电话：0537-2271888 网址：http://www.lkpc.com

国药准字H20003027

0.25g x 24粒

Cefradine Capsules 0.25g [In Foreign Language]

Figure 5. 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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Director General

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