



14 OCT 2021

**FDA ADVISORY**  
No. 2021-2516

**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 Ganmao Ruanjiaonang [as reflected in the package insert]
2. OTC Feining Keli [as reflected in the package insert]
3. Jingu Zhi Tong Gao

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

**康欣诺泰®** 感冒软胶囊 26粒

**康欣诺泰®** 感冒软胶囊说明书

【药品名称】  
总名：感冒软胶囊  
汉语拼音：Ganmao Ruanjiaonang  
【成 份】麻黄、桂枝、荆芥穗、黄芩、苦杏仁、羌活、防风、白芷、石膏、葛根、薄荷、当归、桔梗。辅料为植物油、蜂蜡、胶囊用明胶、甘油、羟苯乙酮、色素。  
【性 状】本品为软胶囊，内容物为深棕色块状液体；气香，味苦、辛。  
【功能主治】散风解热。用于外感风寒引起的头痛发热，鼻塞流涕，恶寒无汗，骨节酸痛，咽喉肿痛。  
【规 格】每粒装0.425克（相当于总药材1.8克）。  
【用法用量】口服。一次2-4粒，一日2次。  
【不良反应】尚不明确。  
【禁 忌】尚不明确。  
【注意事项】

**OTC Ganmao Ruanjiaonang [as reflected in the package insert]**

Figure 1. Unregistered drug product





Figure 2. Unregistered drug product



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 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 <http://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](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto: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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