



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2019-387

15 OCT 2019

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 ORYZANOL TABLETS
2. FEBUXOSTAT TABLETS
3. AOLITAI ORNIDAZOLE CAPSULES
4. ROXITHROMYCIN CAPSULES
5. OMEPRAZOLE SODIUM FOR INJECTION
6. ADENOSINE DISODIUM TRIPHOSPHATE INJECTION
7. JUCISHAN DEXAMETHASONE SODIUM PHOSPHATE INJECTION
8. CEFTRIAZONE SODIUM FOR INJECTION
9. ALLOPURINOL TABLETS
10. CEFOTAXIME SODIUM FOR INJECTION
11. ZX MOROXYDINE HYDROCHLORIDE TABLETS
12. HUAN QIU FLUCONAZOLE AND SODIUM CHLORIDE INJECTION
13. OTC FISHING PILL
14. LUNDBECK FLUPENTIXOL AND MELITRACEN TABLETS (DEANXIT)
15. ITRACONAZOLE HYDROCHLORIDE CAPSULES
16. NEW LINDANE CREAM
17. LUTEIN
18. OTC PENTOXYVERINE CITRATE TABLETS
19. OXYTETRACYCLINE TABLETS
20. OTC FUFANGGANMAOLINGPIAN
21. DIPYRIDAMOLE TABLETS
22. OTC FUMASUAN TONGTIFEN PIAN
23. OTC HOUKANG SAN
24. OTC WEI C YINQIAO PIAN
25. OTC [Label in Foreign Language]
26. XCQM XUECHA QINGMU
27. YABANG GROUP CARBAZOCHROME TABLETS
28. ZN MENADIOL DIACETATE TABLETS
29. BAOZHUPAI® [Label in Foreign Language]
30. TRIVITAMINS B TABLETS [as reflected in the package insert]



31. HUANQIU OFLOXACIN EAR DROPS [as reflected in the primary packaging and package insert]
32. PR[®] RACEANISODAMINE TABLETS
33. JINGKANG JIAONANG
34. 1 YI LHENG
35. OTC [Label in Foreign Language]
36. AZITHROMYCIN DISPERSIBLE TABLETS
37. OTC NAPHAZOLINE HYDROCHLORIDE, CHLORPHENAMINE MALEATE AND VITAMIN B₁₂ EYE DROPS EYE SIGHT
38. KOUQIANGYAN PENWUJI
39. OTC NYTH
40. OTC ACUTE BRONCHITIS SYRUP
41. OTC HUAHONG[®] XIAOZHONGZHITONGDING
42. YUNNAN BAIYAO JIAONANG
43. LOMEFLOXACIN HYDROCHLORIDE EYE DROPS
44. OTC [Label in Foreign Language]
45. OTC LORATADINE TABLETS [as reflected in the package insert]
46. SPH DING LU BRAND[®] QINGGAN CHUANXINLIAN PIAN
47. OTC 999[®] ZHENGtian WAN

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



OTC Oryzanol Tablets

Figure 1. Unregistered drug product

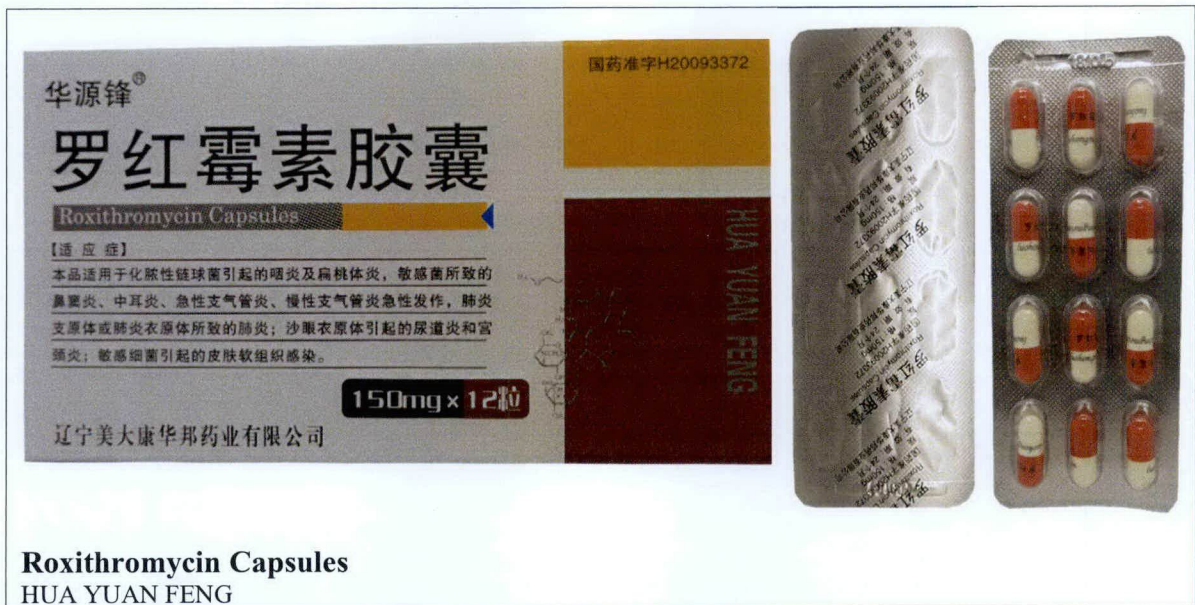


Febuxostat Tablets
Figure 2. Unregistered drug product



AOLITAI ORNIDAZOLE CAPSULES
Xi'an Wanlong Pharmaceutical Company, Ltd

Figure 3. Unregistered drug product




Roxithromycin Capsules
 HUA YUAN FENG

Figure 4. Unregistered drug product



Omeprazole Sodium for Injection
 HUNAN WZT PHARMACEUTICAL CO., LTD.

Figure 5. Unregistered drug product



三磷酸腺苷二钠注射液

ADENOSINE DISODIUM TRIPHOSPHATE INJECTION

2ml×10支

国药准字H35020101

【性状】 本品为无色至微黄色的澄明液体。

【成份】 三磷酸腺苷二钠。

【适应症】 辅酶类药物。用于进行性肌萎缩、脑出血后遗症、心功能不全、心肌疾患及肝炎等的辅助治疗。

【用法用量】 肌内注射或静脉注射，一次10~20mg，一日10~40mg。

【禁忌】 本药对窦房结有明显抑制作用。因此对房室综合征、窦房结功能不全者及老年人慎用或不用。

【注意事项】 静注宜缓慢，以免引起头晕、头胀、胸闷及低血压等。心肌梗死和脑出血患者在发病期慎用。


【不良反应】

【贮藏】 凉暗处(避光并不超过20℃)密闭保存。

【规格】 2ml:20mg(按C₁₀H₁₆N₅Na₂O₁₃P₃计)


【包装】 安瓿装，10支/盒

福建古田药业有限公司



ADENOSINE DISODIUM TRIPHOSPHATE INJECTION

Figure 6. Unregistered drug product



地塞米松磷酸钠注射液

Dexamethasone Sodium Phosphate Injection

国药准字H41020055

【成份】 本品主要成份为：地塞米松磷酸钠，辅料为：磷酸氢二钠、亚硫酸氢钠、丙二醇、注射用水。

【性状】 本品为无色的澄明液体。

【适应症】 主要用于过敏性与自身免疫性炎症性疾病。多用于结缔组织病、活动性风湿病、类风湿性关节炎、红斑狼疮、严重支气管哮喘、严重皮炎、溃疡性结肠炎、急性白血病等，也用于某些严重感染及中毒、恶性肿瘤的综合治疗。


【用法用量】 一般剂量静脉注射每次2~20mg；静脉滴注时，应以5%葡萄糖注射液稀释，可2~6小时重复给药至病情稳定，但大剂量连续给药一般不超过72小时。还可用于缓解恶性肿瘤所致的脑水肿，首剂静脉推注10mg，随后每6小时肌内注射4mg.....详见说明书。

【不良反应】、**【禁忌】**、**【注意事项】** 详见说明书。

【贮藏】 避光，密闭保存。

郑州卓峰制药有限公司

ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO.,LTD.



JUCISHAN Dexamethasone Sodium Phosphate Injection
ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD.

Figure 7. Unregistered drug product



Figure 8. Unregistered drug product



Figure 9. Unregistered drug product

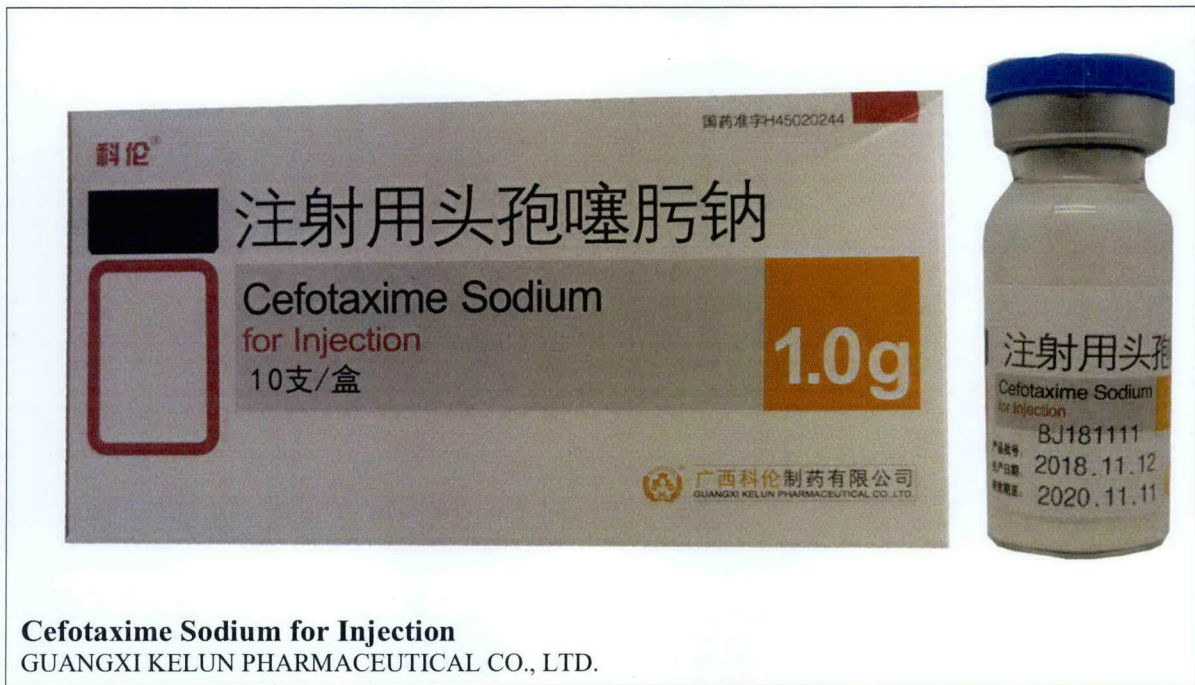


Figure 10. Unregistered drug product



Figure 11. Unregistered drug product



Figure 12. Unregistered drug product



OTC Fishing Pill

Lee Buan Soa Dispensary (Fishing Brand) Ltd., Part. - 49/50 Leamchabang Industrial Estate Moo 5, Toongsukhla Sub-District, Sriracha District, Cholburi 20230, Thailand

Figure 13. Unregistered drug product



LundBbeck Flupentixol and Melitracen Tablets (Deanxit)

H. LlundBbeck A/S - Ottiliavej 9, DK-2500, Valby, Denmark

Figure 14. Unregistered drug product

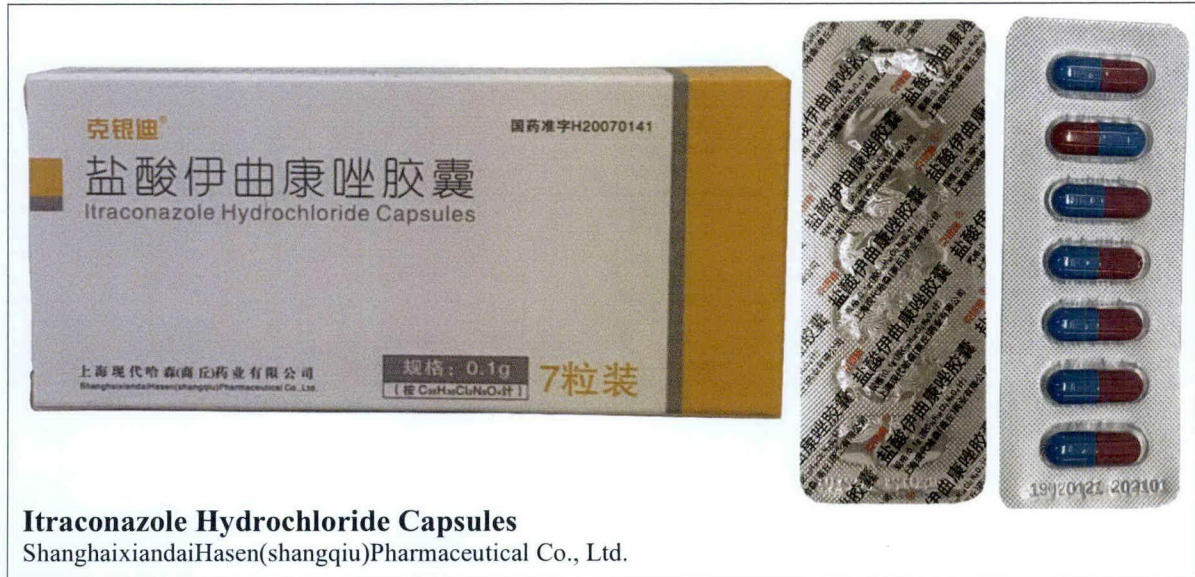


Figure 15. Unregistered drug product



Figure 16. Unregistered drug product



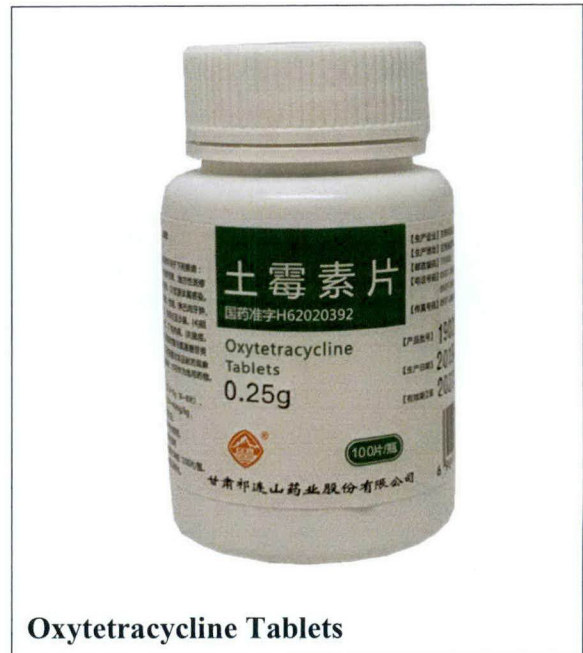
LUTEIN

Figure 17. Unregistered drug product



OTC Panloxyverine Citrate Tablets

Figure 18. Unregistered drug product



Oxytetracycline Tablets

Figure 19. Unregistered drug product



OTC (FUFANGGANMAOLINGPIAN)
Guangxi jinnuozhi yaoyouxian gongsi

Figure 20. Unregistered drug product



Dipyridamole Tablets
YABAO PHARMACEUTICAL GROUP CO.,LTD.

Figure 21. Unregistered drug product



OTC Fumasuan Tongtifen Pian

Figure 22. Unregistered drug product



OTC Houkang San

Figure 23. Unregistered drug product



OTC WEI C YINQIAO PIAN

Figure 24. Unregistered drug product



OTC [Label in Foreign Language]
CISEN

Figure 25. Unregistered drug product



Figure 26. Unregistered drug product

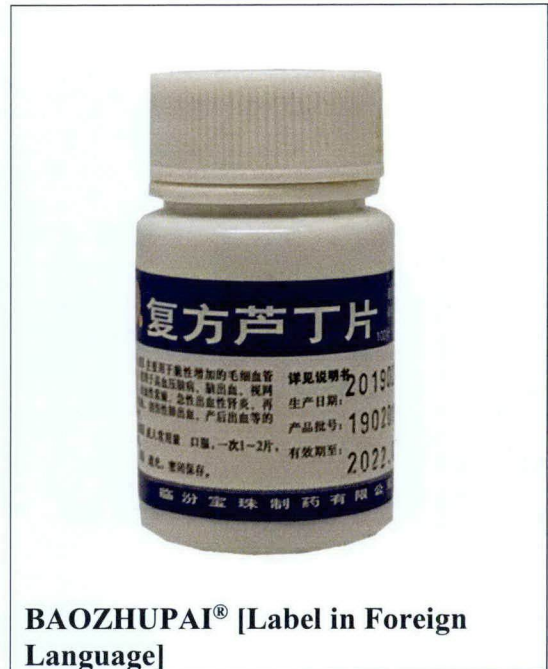


Figure 27. Unregistered drug product



ZN Menadiol Diacetate Tablets

Figure 28. Unregistered drug product



BAOZHUPAI® [Label in Foreign Language]

Figure 29. Unregistered drug product



Trivitamins B Tablets [as reflected in the package insert]

Figure 30. Unregistered drug product



HUANQIU Ofloxacin Ear Drops [as reflected in the primary packaging and package insert]

Figure 31. Unregistered drug product



PR® RACEANISODAMINE TABLETS
HENANPURUIZHUYAOUYUOXIANGONGSI

Figure 32. Unregistered drug product



Figure 33. Unregistered drug product



Figure 34. Unregistered drug product



OTC [Label in Foreign Language]

Figure 35. Unregistered drug product



Azithromycin Dispersible Tablets

Figure 36. Unregistered drug product



OTC Naphazoline Hydrochloride, Chlorphenamine maleate and Vitamin B₁₂ Eye Drops Eye Sight
 SHIJIAZHUANGGREATPHARMACEUTICALCO.,LTD

Figure 37. Unregistered drug product



Kouqiangyan penwuji

Figure 38. Unregistered drug product

NYTH 宛衡

OTC

请仔细阅读说明书并按说明使用或在药师指导下购买和使用

批准文号：国药准字H19994088

氢溴酸右美沙芬片

适应症：用于干咳，包括上呼吸道感染（如感冒和咽炎）、支气管炎等引起的咳嗽。

北京天衡药物研究院南阳天衡制药厂 1×24片/板/盒

OTC NYTH

Figure 39. Unregistered drug product



OTC Acute Bronchitis Syrup

TAIJI GROUP, CHONGQING FULING PHARMACEUTICAL FACTORY CO., LTD

Figure 40. Unregistered drug product



OTC HUAHONG® XIAOZHONGZHITONGDING

Figure 41. Unregistered drug product



Figure 42. Unregistered drug product



Figure 43. Unregistered drug product



Figure 44. Unregistered drug product



Figure 45. Unregistered drug product



Figure 46. Unregistered drug product



Figure 47. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration and testing 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 and safety. The consumption of such violative products may pose potential danger or injury if administered.

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.

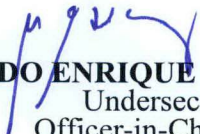
In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against it. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

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 report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number (02)809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.


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Officer-in-Charge, Director General

DTN: 

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