



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. 2020-1262

JUN 29 2020

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 Banlangen Keli Sachets 20's
2. OTC Ankahuangmin Jiaonang TS® - Paracetamol, Caffein, Artificial Cow-bezoar and Chlorphenamine Maleate Capsule [as reflected in the package insert]
3. OTC Fuke Tiaojing Pian Tablet [as reflected in the package insert]
4. [Label in foreign language]
5. D.B.S® Yunsuan Anxiusuo Putaotang Zhushey - Ambroxol Hydrochloride and Glucose Injection Vial 100 ml [as reflected in the package insert]
6. HASEN® Yansuan Leinitiding Zhushey - Ranitidine Hydrochloride Injection Ampoule 2ml:50mg
7. Zhusheyong Lai'anpilin - Lysine Acetylsalicylate for Injection Vial 0.9g [as reflected in the package insert]
8. OTC Fufang Banlangen Keli Sachet 10's [as reflected in the package insert]
9. Aomeilazuo Changrong Jiaonang - Omeprazole Enteric-coated Capsule 20mg [as reflected in the package insert]
10. SHANGYUAN® Gaomengsuanjia
11. Levofloxacin Lactate and Sodium Chloride Injection - Rusuan Zuoyangfushaxing Lvhuana Zhushey 100 ml [as reflected in the package insert]
12. Fu Bang Fu Kang Zuo Jiao Nang (Secondary packaging) Fluconazole Capsule 50 mg (Primary packaging)
13. OTC Huoxiang Zhengqi Jiaonang Capsule
14. Fu Bang Luo Hong Mei Su Jiao Nang 150 mg Capsule
15. China Time-honored Brand Paishi Keli 20g Sachet [as reflected in the package insert]
16. OTC shuangzuotai shuan - Metronidazole, Clotrimazole and Chlorhexidine Acetate Suppositories [as reflected in the package insert]
17. Fufang Huangliansu Pian Tablet
18. OTC Jianwei Xiaoshi Pian Tablet [as reflected in the package insert]
19. OTC Newomen® Shier Wujibaifeng Wan Sachet 8's
20. OTC 999® Ganmaoling Keli Sachet 9's
21. Jiantong® Ganmaoqing Jiaonang Capsule

22. Shineway Qingkailing Zhusheyeye Ampoule 10 ml
[as reflected in the package insert]
23. OTC Ke Te Ling Jiao Nang Capsule
24. Danshenzhusheye Ampoule 10 ml
25. OTC Yansuan Anxiusuo Pian - Ambroxol Hydrochloride Tablet [as reflected in the package insert]
26. OTC CISEN® Hongmeisu Yangao - Erythromycin Eye Ointment [as reflected in the package insert]
27. OTC [Label in foreign language]
28. [Label in foreign language] 0.25g
29. OTC [Label in foreign language]
30. OTC Tian Ma Shou Wu Pian 0.5 g Tablet
31. CSPC® [Label in foreign Language] 0.5g Vial
32. JUCISHAN® Jigan Zhusheyeye – Inosine Injection Ampoule 2ml:100mg
33. Progesterone Injection Ampoule 1ml:10 mg

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



Figure 1. Unregistered drug product



Figure 2. Unregistered drug product



Figure 3. Unregistered drug product



Figure 4. Unregistered drug product

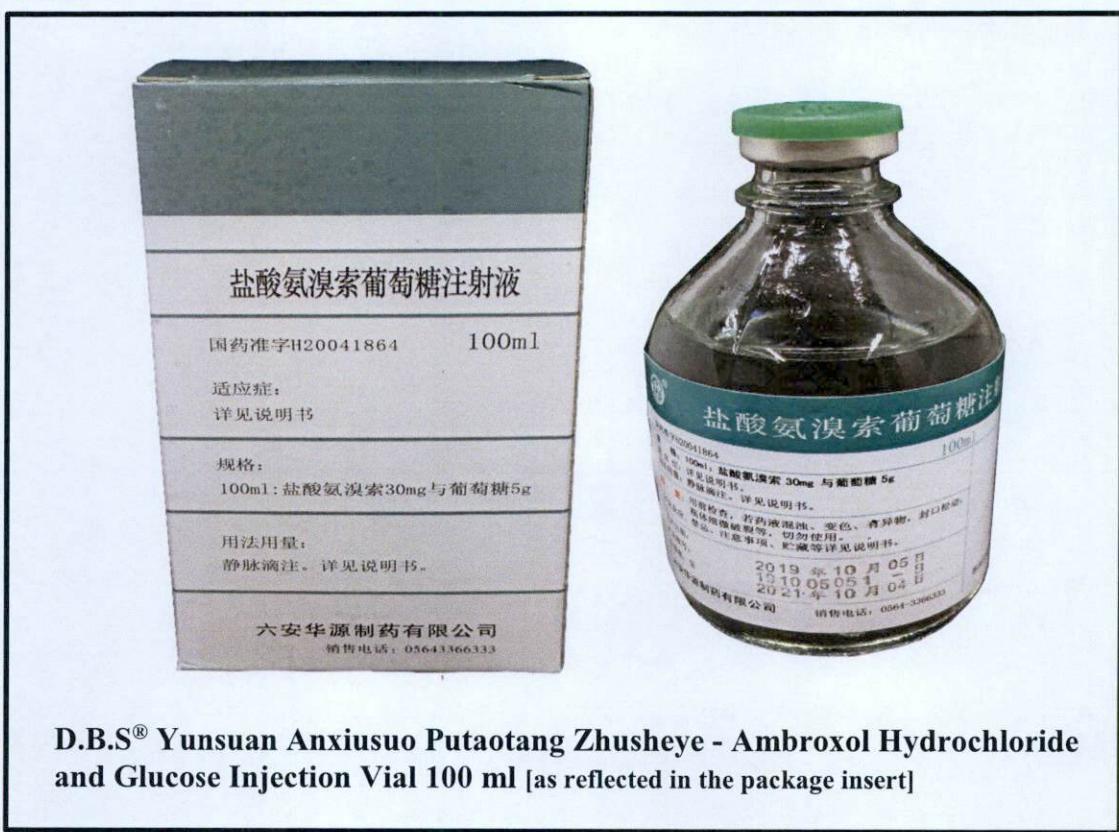


Figure 5. Unregistered drug product

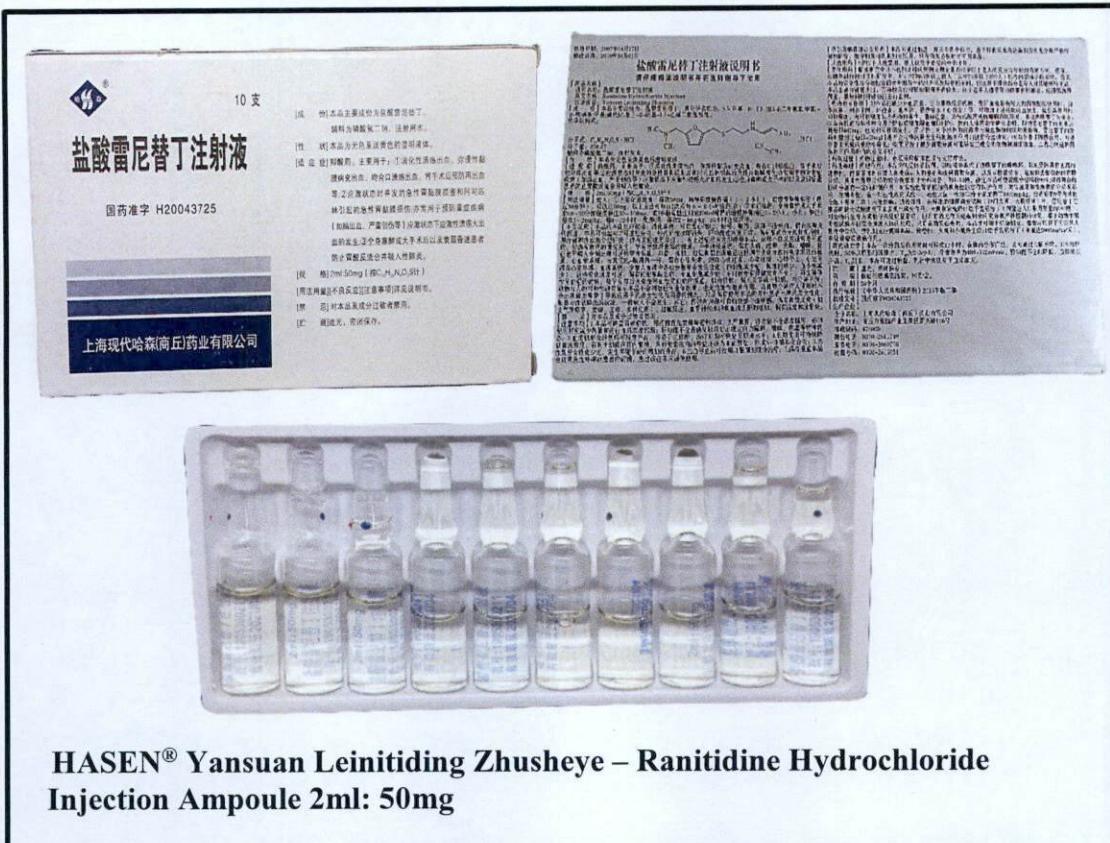


Figure 6. Unregistered drug product



Figure 7. Unregistered drug product



OTC Fufang Banlangen Keli Sachet 10's [as reflected in the package insert]

by: Sichuan Fengchun Pharmaceutical Co., Ltd.

Figure 8. Unregistered drug product



Aomeilazuo Changrong Jiaonang - Omeprazole Enteric-coated Capsule 20mg [as reflected in the package insert]

Figure 9. Unregistered drug product



Figure 10. Unregistered drug product

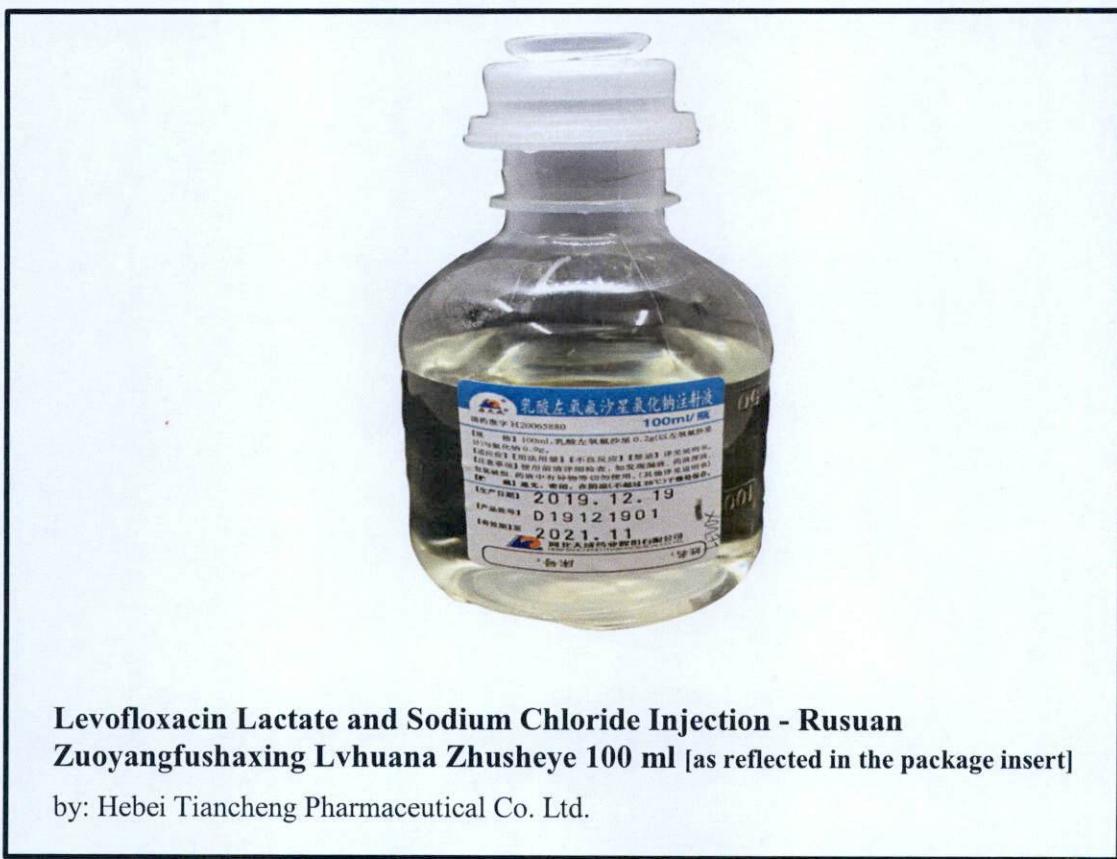


Figure 11. Unregistered drug product



Figure 12. Unregistered drug product



Figure 13. Unregistered drug product



Figure 14. Unregistered drug product



Figure 15. Unregistered drug product



Figure 16. Unregistered drug product



Figure 17. Unregistered drug product



Figure 18. Unregistered drug product



Figure 19. Unregistered drug product



Figure 20. Unregistered drug product



Figure 21. Unregistered drug product



Figure 22. Unregistered drug product



Figure 23. Unregistered drug product



Figure 24. Unregistered drug product



Figure 25. Unregistered drug product



Figure 26. Unregistered drug product



Figure 27. Unregistered drug product



Figure 28. Unregistered drug product



Figure 29. Unregistered drug product



Figure 30. Unregistered drug product



Figure 31. Unregistered drug product



Figure 32. Unregistered drug product



Figure 33. 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 not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee their quality and safety. Therefore, consumption of such violative products may pose potential danger or injury to health.

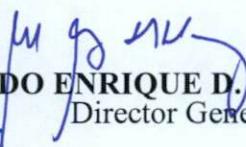
Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

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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