



FDA ADVISORY  
No. **2021-3630**

24 DEC 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. **SBOND Metformin Hydrochloride Sustained- Release Tablets Yansuan Er Jiashuanggua Huanshi Pian [as reflected in the package insert]**
2. **Gentamicin Sulfate Injection – Liusuan Qingdameisu Zhushuye 150 mg**
3. **Baofukang Shuan [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:

**司邦得®** 国药准字H20060230

盐酸二甲双胍缓释片  
圣邦杰

0.5克/片X30片

**SBOND** 山东司邦得制药有限公司

批准日期: 2007年11月15日  
修改日期: 2008年07月18日  
2010年09月09日  
2013年11月04日  
2015年11月26日  
2016年04月27日  
2020年03月23日

**盐酸二甲双胍缓释片说明书**  
请仔细阅读说明书并在医师指导下使用。

【药品名称】  
通用名称: 盐酸二甲双胍缓释片  
商品名称: 圣邦杰  
英文名称: Metformin Hydrochloride Sustained-release Tablets  
汉语拼音: Yansuan Er Jiashuanggua Huanshi Pian  
【成份】本品主要成份为盐酸二甲双胍, 其化学名称为: 1, 1-二甲双胍盐酸盐。  
化学结构式:  
CN(C)C(=N)N

分子式:  $C_4H_{11}N_5 \cdot HCl$   
分子量: 165.63

【性状】本品为类白色片。  
【适应症】适用于单用饮食和运动治疗不能获得良好控制型的2型糖尿病患者。本品可单独使用, 也可与磺脲类或胰岛素合用。  
【规格】0.5g(以盐酸二甲双胍计)

**SBOND Metformin Hydrochloride Sustained- Release Tablets  
Yansuan Er Jiashuanggua Huanshi Pian [as reflected in the package insert]**

Figure 1. Unregistered drug







## 硫酸庆大霉素注射液

批准文号：国药准字H37020242

适应症：适用于治疗敏感革兰阴性杆菌所致的严重感染，用丁敏感细菌所致中枢神经系统感染时，可同时用本品鞘内注射作为辅助治疗。详见说明书。

**烟台鲁银药业有限公司**  
山东省烟台市白石路102号






**Gentamicin Sulfate Injection – Liusuan Qingdameisu Zhushuye 150 mg**

Figure 2. Unregistered drug



## 保妇康栓

【批准文号】国药准字Z46020058 **外**

8粒/盒

【功能主治】行气破瘀，生肌止痛。用于湿热瘀滞所致的带下病，症见带下量多、色黄、时有阴部瘙痒；霉菌性阴道炎、老年性阴道炎、宫颈糜烂见上述证候者。



核准日期：2007年01月31日  
修改日期：2018年04月10日

**保妇康栓 说明书**  
请仔细阅读说明书并在医师指导下使用

【药品名称】  
通用名称：保妇康栓  
汉语拼音：Baofukang Shuan

【成份】  
本品系乳白色、乳黄色或棕黄色的子热片。

【性状】  
行气破瘀，生肌止痛。用于湿热瘀滞所致的带下病，症见带下量多、色黄、时有阴部瘙痒；霉菌性阴道炎、老年性阴道炎、宫颈糜烂见上述证候者。

【规格】  
每粒重：74g。

【用法用量】  
洗净外阴部，将栓剂置入阴道深部；或在医生指导下用药用，每晚1粒。  
用法说明：1、洗净双手及外阴，擦去阴唇，取出药栓（见图1、图2）。

**Baofukang Shuan [as reflected in the package insert]**  
by: Hainan Bikai Pharmaceutical Co., Ltd.

Figure 3. Unregistered drug



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 <https://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.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

DTN:



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