

**FDA ADVISORY**  
No. **2024-0743**

03 MAY 2024

**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 JUCISHAN® Sodium Cromoglicate Eye Drops**
2. **GUANG HUI Compound Ketoconazole Cream**
3. **Chlorzoxazone Tablets 0.2g**
4. **JUCISHAN® Dexamethasone Sodium Phosphate Injection 1ml:5mg Ampoule**

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



**OTC JUCISHAN® Sodium Cromoglicate Eye Drops**  
Manufactured by: Zhengzhou Zhuofeng Pharmaceutical Co., Ltd.

Figure 1. Unregistered drug product





**GUANG HUI Compound Ketoconazole Cream**

Figure 2. Unregistered drug product



**Chlorzoxazone Tablets 0.2g**

Figure 3. Unregistered drug product



国药准字H41020055

## 地塞米松磷酸钠注射液

Dexamethasone Sodium Phosphate Injection

**【成份】**本品主要成份为：地塞米松磷酸钠。辅料为：磷酸氢二钠十二水合物、亚硫酸氢钠、丙二酸、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，恶性淋巴瘤的综合治疗。

**【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，还可用于缓解急性肿瘤所致的水肿，首剂静脉推注10mg，随后每6小时肌肉注射4mg...详见说明书。

**【不良反应】**、**【禁忌】**、**【注意事项】**详见说明书。

**【贮藏】**遮光，密闭保存。

1ml:5mg 10支

**郑州卓峰制药有限公司**  
ZHENGZHOU ZHUOFENG PHARMACEUTICAL CO., LTD

**地塞米松磷酸钠注射液说明书**

请仔细阅读说明书并在医师指导下使用

【药品名称】  
通用名：地塞米松磷酸钠注射液  
英文名：Dexamethasone Sodium Phosphate Injection  
商品名：JUCISHAN  
【性状】本品为无色的澄明液体，遇光色变深，久置有沉淀，可过滤后使用。

【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，恶性淋巴瘤的综合治疗。

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【不良反应】、【禁忌】、【注意事项】详见说明书。

【贮藏】遮光，密闭保存。





**JUCISHAN<sup>®</sup> Dexamethasone Sodium Phosphate Injection 1ml:5mg Ampoule**  
Manufactured by: Zhengzhou Zhuofeng Pharmaceutical Co., LTD.

Figure 4. 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 <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://bit.ly/FDAPHReportSideEffect> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
**DR. SAMUEL A. ZACATE**  
Director General

DTN:



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