

# **Medical Product Alert No. 01/ 2024**

## **Unregistered Medical Products with Chinese Labels in Supermarkets in Ghana**

### **Alert Summary**

The Food and Drugs Authority (FDA), Ghana reports of unregistered Chinese-labelled medicines sold in identified supermarkets in the Greater Accra Region of Ghana. The products were detected during Market Surveillance (MS) activities in some Chinese supermarkets in Tema .

Classes of medicines found in the supermarkets are Analgesics, Antibiotics, Antihelmintics and Antipsychotics. The medicines are classified as Over-the-Counter Medicines (OTCs) and Prescription- Only Medicines (POMs). The FDA has taken the necessary regulatory sanctions against the facilities where the medical products were found including seizure of the medicines.

### **How to identify this unregistered products**

To identify these product check for the following:

- The products have inscriptions written in Chinese language only
- Some of the products have no Patient Information Leaflet (PIL) inserted in the product packages
- Products with Patient Information Leaflet (PIL) inserted in the product packages do not have information in English
- The products cannot be found on FDA website or register for list of registered products since they have not been approved by the FDA .

Please refer to the attachment of this Alert for details of the unregistered products.

### **Risks**

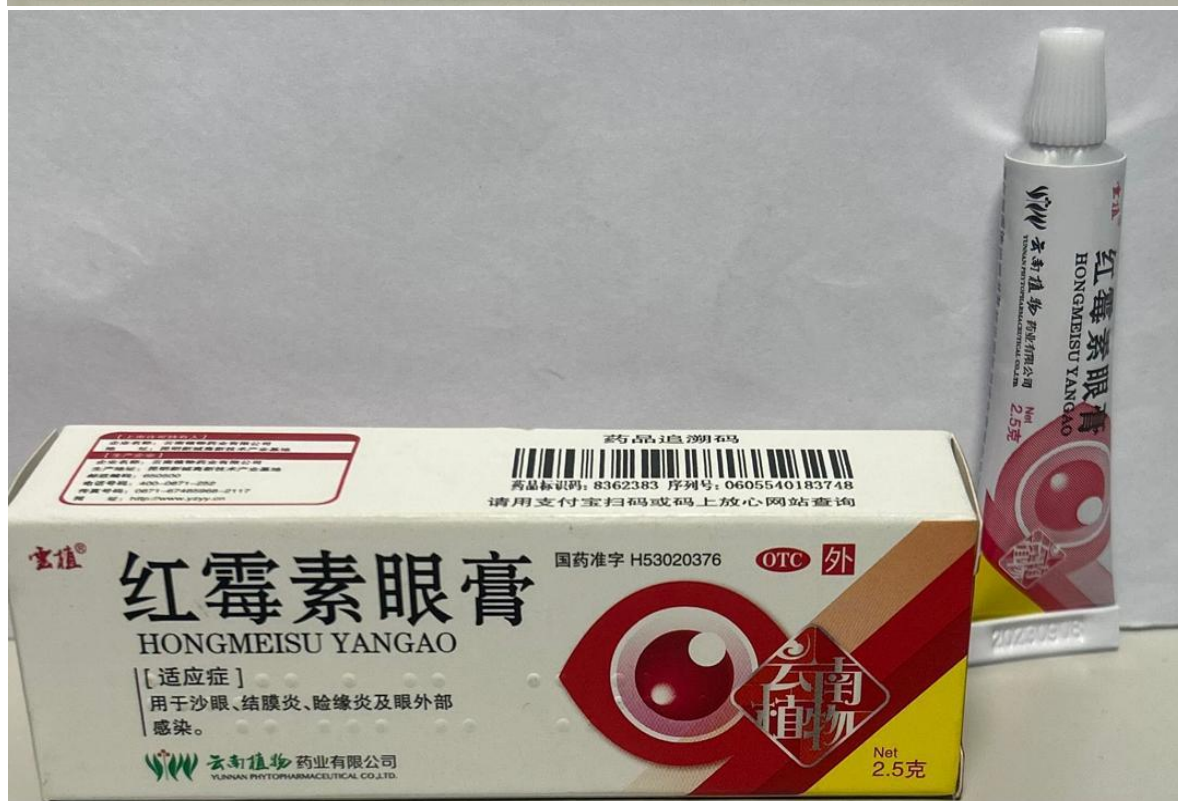
- The unregistered medical products have not been evaluated by the FDA, therefore their safety, quality and efficacy cannot be guaranteed
- The medical products are being dispensed from unlicensed facilities hence the storage conditions cannot be guaranteed
- The products pose significant risk to users since information is not in the official language (English) and critical information such as indications, dosing, expected adverse effects and management, contra-indications cannot be interpreted.

### **Advice to healthcare professionals, regulatory authorities and the public**

If you are in possession any of the products, the FDA recommends that you do not use them and return them to the nearest FDA office or health facility. If you, or someone you know, has, or may have used these products, or suffered an adverse event or unexpected side-effect after use, seek immediate medical advice from a healthcare professional or contact a the FDA in any of our offices or through our social media handles.

Note that all medical products must be obtained from authorized/licensed suppliers and not supermarkets. If you have any information about the supply of these Chinese labelled medical products, please contact the FDA.

## Pictures of products- Alert number: 01/ 2024















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H20031280

OTC

**多潘立酮片**

10毫克 30片

**Domperidone Tablets**

[成份] 本品每片含多潘立酮10毫克。辅料为：乳糖、微晶纤维素、玉米淀粉、硬脂酸镁。

[性状] 本品为白色片。

[适应症] 用于消化不良、腹胀、嗝气、恶心、呕吐、腹部胀痛。

[用法用量] 口服。成人一次1片，一日3次，饭前15~30分钟服用。

[不良反应] 1. 偶见口干、头痛、失眠、神经过敏、头晕、嗜睡、倦怠、腹部痉挛、腹泻、反流、恶心、胃灼热感、皮疹、瘙痒、荨麻疹、口腔炎、结膜炎等。详见说明书。

[禁忌] 1. 机械性消化道梗阻，消化道出血、穿孔患者禁用。详见说明书。

[注意事项] 1. 本品用药3天，如症状未缓解，请咨询医师或药师。药物使用时间一般不得超过1周。详见说明书。

[贮藏] 遮光，密封保存。

[上市许可持有人]、[生产企业]

上海信谊天平药业有限公司

生产地址：上海市闵行区金都路4598号

邮政编码：201108

电话号码：021-54428899

传真号码：021-54425880

如有问题可与上市许可持有人联系



6 927128 710113



