



FDA ADVISORY

No. - **20230409**

10 MAR 2023

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. YUHAN Celestone-G® Cream 30 g [Label in Foreign Language]
2. SAMJIN Geworin® Tablet [as reflected in the package insert]
3. Fucidin Ointment 10 g [Label in Foreign Language]

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





효과 빠른 한국인의 두통약
게보린정
 두통 | 치통 | 생리통 | 오한 | 발열
 Geworin® Tablet

● 유효성분에 포함 : 아세트아미노펜 300mg, 이소부프로펜 150mg, 카페인이 함유되어 있음

● 성분 : 중사의 정제

일반의약품 정보	
이 내용은 소비자의 안전한 선택을 위해 허가사항을 요약한 것으로 사용 전 반드시 첨부문서를 확인하십시오.	
[유효성분]	1정 중 아세트아미노펜(KP) 300mg, 이소부프로펜(KP) 150mg, 카페인이 함유되어 있음 50mg
[효능·효과]	다음 질환의 진통 및 해열시 단일제로 : ● 두통, 치통, 발치(이)를 포함한 동통(등통), 인후(목)구강통, 구의 통증, 관절통, 신경통, 요통(허), 근육통, 건초염(염), 타박상, 골절상, 연골염(염) 등 임, 월경통(생리통), 외상성(상)의 진통 ● 오한(열)과 발열(열)의 해열
[용법·용량]	만 15세 이상의 소아 및 성인 1회 1정 1일 3회까지 공복(속)을 피하여 복용 복용기간은 4시간 이상 휴식(안)으로 24시간 미만 만 15세 미만의 소아 15세 미만의 소아는 이 약을 복용하지 않는다.
[사용상의 주의사항]	● 1정 15세 이상 장기간(연속)이 약 15일 이상 복용할 때는 의사·약사의 상담을 받고, 건강상의 위험할 수 있음 15세 미만의 소아는 이 약을 복용하지 않는다.
[저장방법]	일회용기 실온(15~30°C) 보관, 어린이의 손에 닿지 않는 곳에 보관



SAMJIN Geworin® Tablet [as reflected in the package insert]
 by: Samjin

Figure 2. Unregistered drug product



Fucidin Ointment 10 g [Label in Foreign Language]
 Produced under licensed from Leo Pharma A/S - Ballerup, Denmark

Figure 3. 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. 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.


DR. SAMUEL A. ZACATE
Director General 

DTN: 

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