



FDA ADVISORY

No. 2022-1483-A

29 JUL 2022

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Sumusunod na Hindi Rehiistradong Gamot:

1. **BAYER Redoxon® VitaminC 15 Orange Flavour Effervescent Tablets [Label in Foreign Language]**
2. **GSK Panadol® Cold+Flu Day 24 Caplets [Label in Foreign Language]**
3. **GSK Panadol® ActiFast™ 20 Tablets [Label in Foreign Language]**

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na hindi rehiistradong gamot:

BAYER Redoxon® VitaminC 15 Orange Flavour Effervescent Tablets
[Label in Foreign Language]
by: Delpharm Gaillard, France

Larawan 1. Hindi rehiistradong gamot



COLD+FLU
Panadol DAY
For effective relief from:
Blocked & runny nose ✓
Headache & body ache ✓
Fever ✓
24 CAPLETS

كولد+فلو
بانادول
داي
لعلاج فعال من:
انسداد وسيلان الأنف ✓
الصداع و آلام الجسم ✓
الحمى ✓
علاج فعال لآعراض البرد والإنفلونزا، لا يسبب الاعاس

GTIN 06291107430843
Panadol COLD+FLU DAY
THE EFFECTIVE DAY-TIME COLD & FLU REMEDY WITHOUT CAUSING DROWSINESS
CONTAINS PARACETAMOL
يحتوي على الباراسيتامول
Do not take with any other pain-relieving products.
Keep medication out of reach and sight of children.
Protect from light and heat. Store in the original container.
This product is presented in a sealed blister. Do not use if blister is broken. Store below 25°C.
لا تأخذ مع أي منتجات أخرى لتخفيف الألم.
حفظ الدواء بعيداً عن متناول الأطفال.
حفظ الدواء بعيداً عن الضوء والحرارة. خزن الدواء في العبوة الأصلية.
هذا المنتج معروض في عبوة مغلقة. لا تستخدم إذا كان الغلاف مكسوراً. خزن الدواء في درجة حرارة أقل من 25 درجة مئوية.

CAUTION
Do not exceed the stated dosage. If symptoms persist, consult your doctor. For professional advice on medicine consult your pharmacist. It contains aspirin before E 100.
لا تتجاوز الجرعة المحددة.
إذا استمرت الأعراض، استشر الطبيب.
للحصول على نصيحة مهنية بشأن الأدوية استشر الصيدلي.
يحتوي على الأسبرين قبل E 100.

INGREDIENTS
Each Panadol Cold + Flu Day caplet contains:
Paracetamol Ph. Eur. 500mg, Phenylephrine Hydrochloride BP 5mg, Caffeine Ph. Eur. 25mg

GlaxoSmithKline, Dungarvan Ltd., Ireland.
Panadol is a registered trade mark of the GlaxoSmithKline group of companies.

0882 9207

Paracetamol 500mg, Phenylephrine Hydrochloride 5mg, Caffeine 25mg. USE ONLY IF FOIL SEAL IS INTACT.

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GSK Panadol® Cold+Flu Day 24 Caplets [Label in Foreign Language]
Manufacturer: GlaxoSmithKline, Dungarvan Ltd., Ireland

Larawan 2. Hindi rehistradong gamot

Panadol ActiFast
FAST effective pain relief ✓
Gentle on stomach ✓
20 TABLETS

ActiFast
500mg Paracetamol
6200000014413

INDICATIONS
Panadol ActiFast is a pain-reliever which is absorbed twice as fast as regular paracetamol. It is effective for the relief of fever and the treatment from mild to moderate pain including headache, migraine, rheumatic and muscular pain, period pain, pain of osteoarthritis, toothache, pain following dental procedures, tooth extraction and pain after vaccination.

DOSAGE
Adults and children aged 12 years old and over: Take 2 tablets up to four times daily. Do not take more frequently than every 4 hours. Do not take more than 8 tablets in 24 hours.
Do not give children under 12 years of age.
Each tablet contains Paracetamol Ph. Eur. 500mg, Sodium content 17mg per tablet.
Do not use with other products containing paracetamol.
This product is Paracetamol & Ibuprofen. Do Not Use if Foil is Broken.

CAUTIONARY NOTE
Please read the enclosed leaflet carefully before taking these tablets. Do not exceed the stated dose. Keep out of reach and sight of children. If symptoms persist consult your doctor for professional advice on medicines. Consult your pharmacist. Store in original container. Protect from light and heat. Store below 25°C. Panadol is a registered trade mark of the GlaxoSmithKline group of companies.

GlaxoSmithKline, Dungarvan Ltd., Ireland.

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ActiFast is a registered trade mark of the GlaxoSmithKline group of companies.

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GSK Panadol® ActiFast™ 20 Tablets [Label in Foreign Language]
Manufacturer: GlaxoSmithKline, Dungarvan Ltd., Ireland

Larawan 3. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang mga nasabing gamot ay hindi dumaaan sa proseso ng rehistrasyon ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Dahil dito, hindi masisiguro ng Ahensya ang kalidad, kaligtasan at bisa nito. Samakatuwid, ang paggamit ng nasabing mga ilegal na produkto ay maaaring magdulot ng panganib sa kalusugan.

Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag. Ugaliing tignan kung rehistrado ang produkto sa FDA sa pamamagitan ng *FDA Verification Portal feature* na makikita sa <https://verification.fda.gov.ph>.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaaring mag-email sa info@fda.gov.ph. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong gamot, mag-email sa ereport@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong (02) 8809-5596. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: <https://primary-reporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.


DR. OSCAR G. GUTIERREZ, JR.
Officer-in-Charge Director General

DTN:



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