



15 JUL 2021

**FDA ADVISORY**  
No. **2021-1792**

**TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

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

- GSK Panadol Flu & Batuk Paracetamol, Phenylephrine HCl, Dextromethorpan HBr 1 Blister @ 10 Kaplets**
- BAYER Membantu Menjaga Kesehatan Tulang CDR® Kalsium, Vitamin D, C & B6 4600 mg 10 Tablet Effervescent**


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



**GSK Panadol Flu & Batuk Paracetamol, Phenylephrine HCl, Dextromethorpan HBr 1 Blister @ 10 Kaplets**  
by: PT Glaxo Wellcome Indonesia, Jakarta, Indonesia

Figure 1. Unregistered drug product





**MEMBANTU MENJAGA KESEHATAN TULANG**

# CDR<sup>®</sup>

**KALSIUM, VITAMIN D, C & B6**

**Rasa Jeruk Mandarin**  
Suplemen Makanan  
10 Tablet Effervescent  
Netto @ 4600 mg



CDR

**Kegunaan:**  
Suplementasi Kalsium, Vitamin C, D & B6 agar tulang sehat pada orang dewasa serta membantu memenuhi kebutuhan kalsium pada ibu hamil dan menyusui. Juga diperlukan untuk masa pertumbuhan, masa penyembuhan, serta gangguan penyerapan makanan.

**Peringatan:**  
- Mengandung pemanis buatan sucralose dan acesulfame potassium.  
- Produk ini tidak boleh digunakan oleh bayi di bawah 1 tahun.

**Anjuran Pemakaian:**  
1 kali sehari 1 tablet effervescent atau menurut petunjuk dokter.

**Cara Penggunaan:**  
Larutkan tablet effervescent ke dalam segelas air untuk memperoleh minuman effervescent dengan rasa jeruk segar. Sebaiknya diminum segera setelah dilarutkan.

**Penyimpanan:**  
Tutuplah tube dengan rapat dan simpan di tempat kering, di bawah suhu 30°C.

Kode Produksi  
Tanggal Produksi  
Sebaiknya digunakan sebelum  
Lihat tutup karton.

No. Reg. POM SD. 191 554 541

Diproduksi oleh:  
PT Bayer Indonesia  
Jl. Raya Bogor Km 32,  
Depok 16416, Indonesia  
Dengan lisensi dan pengawasan  
Bayer Consumer Care AG, Switzerland

LAYANAN KONSUMEN BAYER  
 0 800 11 888 99  
 bebas pulsa

CDR

Tulang dan gigi kuat  
Tulang kuat diperlukan untuk menunjang aktifitas anda sehari-hari. Kekuatan tulang dapat dipersiapkan sejak dini, yakni dengan memenuhi kebutuhan kalsium anda setiap hari. Jika kekurangan kalsium, tulang bisa tipis dan rapuh di kemudian hari. CDR mengandung kalsium dan vitamin penting lainnya yang berperan dalam proses pembentukan tulang kuat dan sehat. CDR, dengan rasa jeruk segar membantu memenuhi kebutuhan kalsium anda setiap hari bila perlu agar tulang tetap kuat kini dan nanti.

**Setiap tablet effervescent mengandung:**

		% ARG
Kalsium (dalam bentuk Kalsium Karbonat)	250 mg	25 %
Vitamin C	1000 mg	1110 %
Vitamin D	400 IU	50 %
Vitamin B6 HCl	15 mg	950 %

%ARG berdasarkan kebutuhan energi 2150 kkal


**Bahan tambahan:**  
Sucralose, Acesulfame potassium, Aspartartemal 1% CWS/M, Citric acid, Orange flavour, Mandarin flavour, Sodium bicarbonate, Sodium carbonate, Sodium chloride, Malic acid, Sorbitol.

**Bisa dikonsumsi oleh penderita diabetes.**

Bayer



8 994591 010017



**BAYER Membantu Menjaga Kesehatan Tulang CDR<sup>®</sup> Kalsium, Vitamin D, C & B6 4600 mg 10 Tablet Effervescent**  
 by: PT Bayer Indonesia - Jl. Raya Bogor Km 32, Depok 16416, Indonesia Dengan Lisensi Dan Pengawasan Bayer Consumer Care AG, Switzerland

Figure 2. 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 its 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.

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:



20210708095405