Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

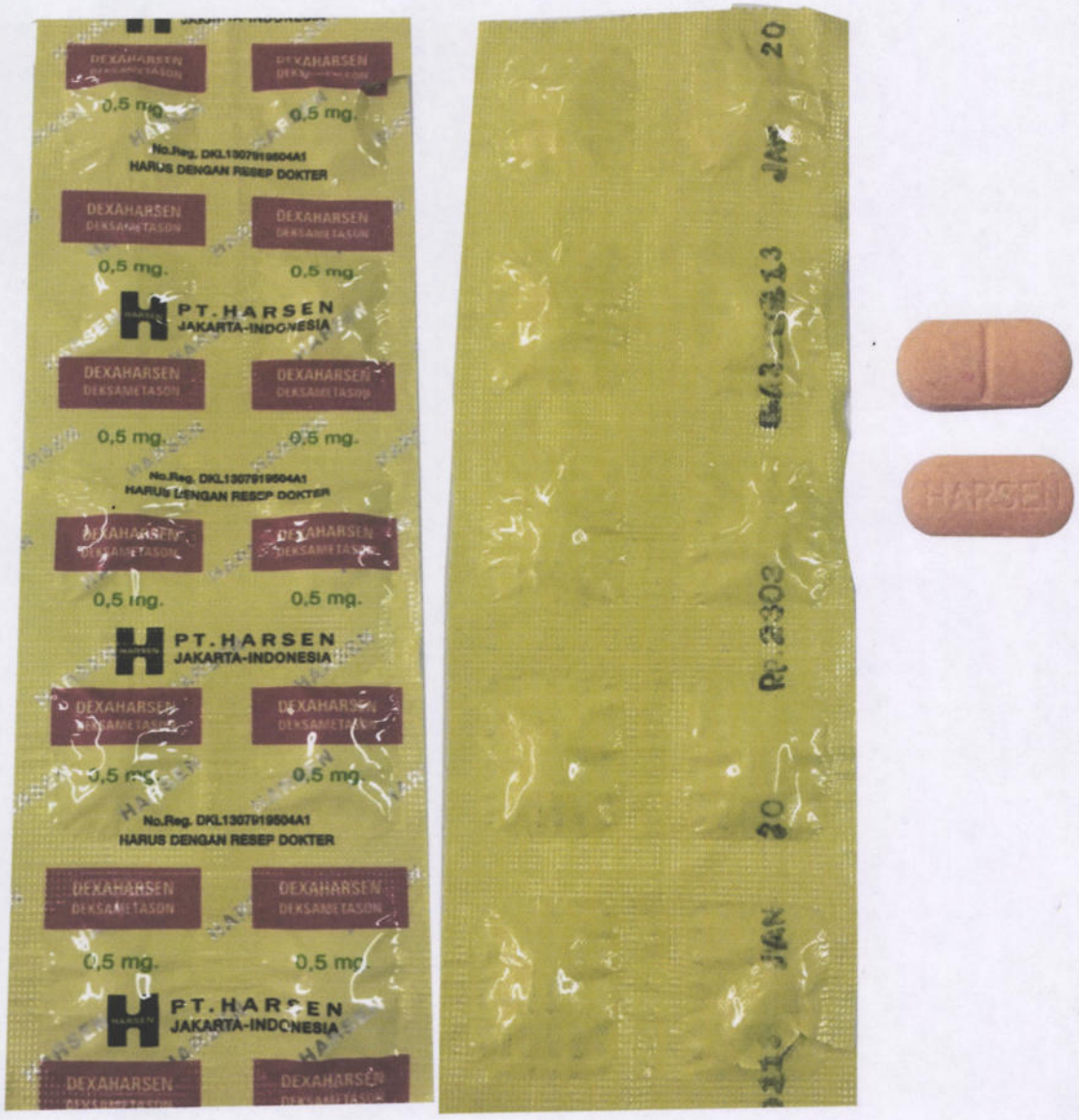
FDA ADVISORY
No. 2016-001

02 FEB 2016

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

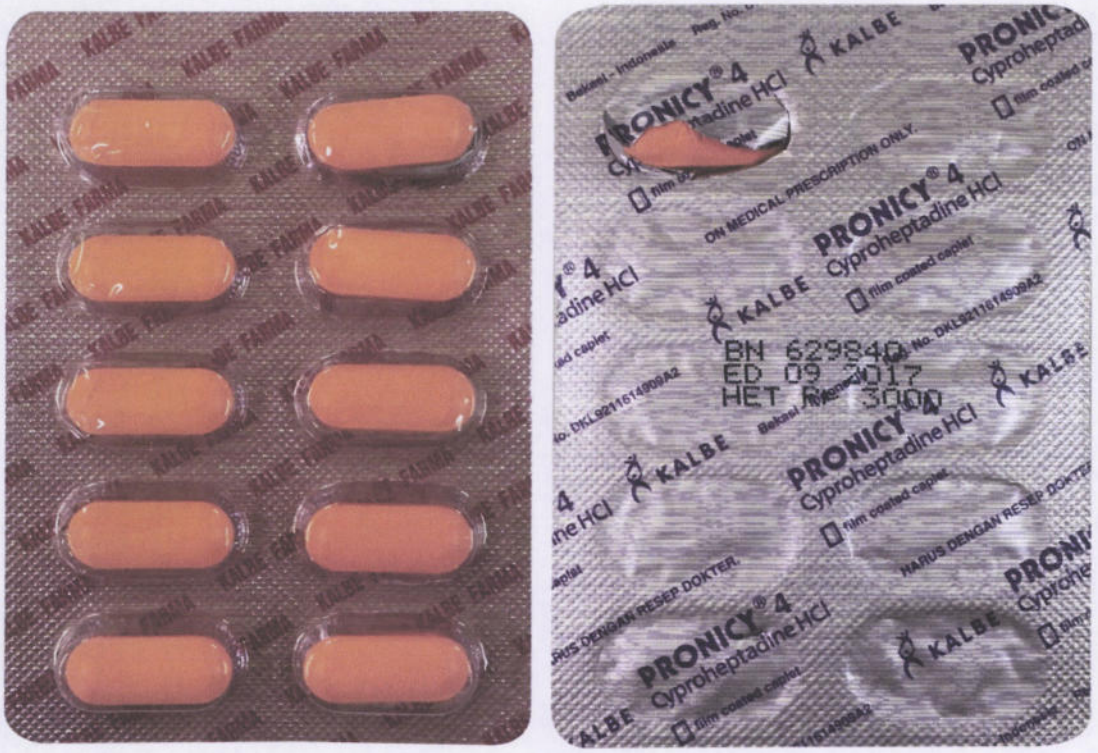
1. **Deksametason (Dexaharsen) 0.5 mg Tablet**
2. **Cyproheptadine HCl (Pronicy 4) Film-Coated Caplet**

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



DEKSAMETASON (DEXAHARSEN) 0.5 MG TABLET
Marketing Authorization Holder: PT. Harsen – Jakarta, Indonesia

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines
Trunk Line +63 2 857 1900 Fax +63 2 807 0751
Website: www.fda.gov.ph Email: info@fda.gov.ph



CYPROHEPTADINE HCL (PRONICY 4) FILM-COATED CAPLET
Marketing Authorization Holder: Kalbe Farma

Figure 1.Unregistered Drug Products

The abovementioned drug products pose potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

The public is hereby advised that **Dexamethasone**, a steroid, and **Cyproheptadine**, an antihistamine, are both classified as prescription drugs required to be purchased only from a licensed drugstore or hospital pharmacy.

The misuse and/or chronic use of steroids like **Dexamethasone** may lead to serious adverse reactions such as:

- Gastrointestinal bleeding and ulcers
- Osteoporosis
- Muscle weakness
- Obesity
- Dyslipidemia
- Increase risk for infection
- Poor wound healing
- Withdrawal signs and symptoms such as hypotension, shock and coma, if stopped abruptly.

Likewise, chronic use of **Cyproheptadine** may lead to the following serious adverse reactions:

- Confusion

- Seizure
- Tinnitus
- Increased appetite
- Hypotension
- Tachycardia
- Difficulty urinating
- Jaundice

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Officers of the Field Regulatory Operations Office (FROO) are hereby ordered to seize the aforementioned unregistered drug products found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified products. Anyone found selling the said products will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration and testing are measures that the government undertakes to ensure the quality, safety and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

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