

Republic of the Philippines Department of Health

FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2016-070

2 8 JUN 2016

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

GENERAL PUBLIC

SUBJECT:

Public Health Warning Against the Use of the Following

Unregistered Drug Products:

1. Trypan Blue (Mede-Blu) Ophthalmic Solution 1 mL

2. Carbachol (CataChol) Intraocular Solution 1 mL

3. Trypan Blue (IO-blue) Ophthalmic Solution 1 mL

4. Carbachol (IO-chol) Intraocular Solution USP 1 mL

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

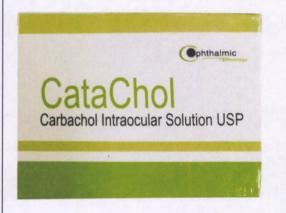




Trypan Blue (Mede-Blu) Ophthalmic Solution 1 mL

Marketing Authorization Holder: MT Promedt Consulting GmbH –

Altenhofstrasse 80, D-66386 St. Ingbert





Carbachol (CataChol) Intraocular Solution 1 mL

Marketing Authorization Holder: Ophthalmic Technology

Figure 1. Unregistered Drug Products







Trypan Blue (IO-blue) Ophthalmic Solution 1 mL

Manufactured for Surgitech Innovation – A-2 Purshotam Garden (Basement) Kunjpura Road, Karnal-132001 Haryana





Carbachol (IO-chol) Intraocular Solution USP 1 mL

Manufactured for Surgitech Innovation – A-2 Purshotam Garden (Basement) Kunjpura Road, Karnal-132001 Haryana

Figure 2. Unregistered Drug Products

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug products. These 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.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

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 e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail 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.

Dissemination of the information to all concerned is requested.

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