

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



23 June 2015

FDA ADVISORY No. 2015~034

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

- Moxifloxacin Hydrochloride (Moxibright) 5 mL Eye Drops
- 2. Moxifloxacin Hydrochloride + Dexamethasone Sodium Phosphate (Moxibright DM) 5 mL Eye Drops
- 3. Carboxymethyl Cellulose Sodium + Glycerin (Tearbright Plus) 10 mL Eye Drops
- 4. Gatifloxacin + Prednisolone Acetate (Gatsun-P) 5 mL Eye Drops
- 5. Moxifloxacin Hydrochloride (Occumox) 5 mL Eye Drops

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



MOXIFLOXACIN HYDROCHLORIDE (MOXIBRIGHT) 5 ML EYE DROPS

Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Simour (H.P.)-173 001





MOXIFLOXACIN HYDROCHLORIDE + DEXAMETHASONE SODIUM PHOSPHATE (MOXIBRIGHT) 5 ML EYE DROPS

Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Simour (H.P.)-173 001

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CARBOXYMETHYL CELLULOSE SODIUM + GLYCERIN (TEARBRIGHT PLUS) 10 mL EYE DROPS

Manufactured by: Sunvet Healthcare – Village Shambhuwala, Paonta Road, Distt. – Simour (H.P.)-173 001



GATIFLOXACIN + PREDNISOLONE ACETATE (GATSUN-P) 5 ML EYE DROPS

Manufactured in India by: Sunways (India) Pvt. Ltd. – Mumbai-400 063



MOXIFLOXACIN HYDROCHLORIDE (OCCUMOX) 5 ML EYE DROPS

Manufactured in India by: Sunways (India) Pvt. Ltd. - Mumbai-400 063

Table 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.

In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Field Regulatory Operations Office (FROO) Officers 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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¹ Pursuant to DPO 2015-1845