



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2019-091**

10 1 APR 2019

TO: ALL HEALTHCARE PROFESSIONALS, RETAIL DRUG OUTLETS, AND THE GENERAL PUBLIC

SUBJECT: Public health alert on the sale/administration/consumption of Nicardipine Hydrochloride 1 mg/mL (10 mg/10 mL) Solution for IV Injection with brand names, Cardilon, Cardimed, & Nicaright, Imported by MedEthix Inc.

In Food and Drug Administration (FDA) Advisory No. 2018-321 dated 26 November 2018, the FDA warned against the administration, sale, and consumption of the following drug products:

| PRODUCT INFO | BRAND NAME | REG. NO. | MANUFACTURER |
|---|------------|-------------|---|
| Nicardipine Hydrochloride 1 mg/mL (10 mg/10 mL) Solution for IV Injection | Nicaright | DRP-5308 | Alvita Pharma Pvt. Ltd. – 136/B Motinagar No. 2, Susen Tarsali Road, Vadodara, Gujarat State, India |
| | Cardilon | DRP-5308-01 | |
| | Cardimed | DRP-5308-02 | |
| | Nicard | DRP-5308-03 | |

In said Advisory, the FDA noted that *Burkholderia cenocepacia*, an aerobic Gram-negative bacillus which emerges as an important opportunistic pathogen in hospitalized and immunocompromised patients was found in a specific batch (5701811) with expiry date: August 2020 of the drug product, Nicardipine Hydrochloride 1 mg/mL (10 mg/10 mL) Solution for IV Injection (Nicard), with Registration No. DRP-5308-03.


Since the drug product, Nicardipine Hydrochloride 1 mg/mL (10 mg/10 mL) Solution for IV Injection with brand name Nicard, and the identical drug products with brand names Nicaright, Cardilon, and Cardimed, were manufactured by Alvita Pharma Pvt. Ltd., the FDA issued the said Advisory against the foregoing drug products pending investigation.

With the conclusion of the investigation, it was determined that only Batch No. 5701811 (Exp. Date: August 2020) of Nicardipine Hydrochloride 1 mg/mL (10 mg/10 mL) Solution for IV Injection with brand name Nicard and Reg. No. DRP-5308-03 was contaminated with *Burkholderia cenocepacia*.

In view of the foregoing findings, **the Advisory against the sale, administration, and consumption of Nicaright, Cardilon, and Cardimed is hereby LIFTED.**



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