Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2020-548-A

06 SEP 2021

TO: **ALL CONCERNED LICENSED ESTABLISHMENTS AND THE GENERAL PUBLIC**

SUBJECT: **AMENDMENT TO FDA ADVISORY NO. 2020-548 "DIRECTIVES FOR RANITIDINE-CONTAINING PRODUCTS" DATED 07 APRIL 2020**

The Food and Drug Administration (FDA) hereby advises the concerned licensed establishments and the general public that the list of compliant ranitidine-containing products relative to the levels of N-nitrosodimethylamine (NDMA) which are allowed to be sold are updated as follows:

PRODUCT INFORMATION	REG. NO.
Ranitidine Hydrochloride 25 mg/mL Solution for Injection (IM/IV) (Siutec)	DR-XY31808
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Nelstac)	DRP-7171
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Ranistar)	DRP-7171-01
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Aglotac)	DRP-6135
Ranitidine (as hydrochloride) 25 mg/mL Sterile Solution for Injection (IM/IV) (Danitin)	DRP-1107
Ranitidine (as hydrochloride) 25 mg/mL Sterile Solution for Injection (IM/IV) (Dynastin)	DRP-1107-01
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Aciloc)	DRP-869
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Eastidine)	DRP-869-01
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Hacidac)	DRP-869-02
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Apo-tin)	DRP-6304
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Primudine)	DRP-6304-01
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Solution for Injection (Entac)	DR-XY29322
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Solution for Injection (IM/IV) (Ulcin)	DR-XY19686
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile	DRP-159

Solution for Injection (IM/IV) (Qualran)	
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Effedine)	DRP-159-03
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Zantricid)	DRP-159-04
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Amkodine)	DRP-159-05
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Geoxer)	DRP-159-06
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Westran)	DRP-159-07
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV) (Ranipen)	DRP-159-09
Ranitidine (as hydrochloride) 150 mg Tablet (Contracid)	DRP-1237
Ranitidine (as hydrochloride) 150 mg Tablet (Ranae)	DRP-1237-01
Ranitidine (as Hydrochloride) 150 mg Tablet (Radine)	DR-XY32319
Ranitidine 150 mg Film-Coated Tablet (Zilatec)	DRP-4651
Ranitidine (as hydrochloride) 300 mg Film-Coated Tablet (Alcera)	DRP-4494
Ranitidine Hydrochloride + Tripotassium Bismuth Dicitrate + Sucralfate 84 mg/100 mg/300 mg Film-Coated Tablet (Albis)	DR-XY44001
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Solution for Injection (Alflux)	DRP-7635
Ranitidine (as Hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Ranidex)	DR-XY39911
Ranitidine Hydrochloride 25 mg/mL (50 mg /2 mL) Solution for Injection (IM / IV) (Zantol)	DR-XY40614
Ranitidine Hydrochloride 25 mg/mL Solution for Injection (Ameket)	DR-XY28707
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (Ranitein)	DRP-2017
Ranitidine Hydrochloride 50 mg/2 mL Sterile Solution for Injection (IM/IV) (Contracid)	DRP-655
Ranitidine (As Hydrochloride) 150 mg Film Coated Tablet (Ranitein)	DRP-1857
Ranitidine (As Hydrochloride) 150 mg Film Coated Tablet (Ratidin)	DRP-1857-01
Ranitidine (As Hydrochloride) 300 mg Film Coated Tablet (Ranitein)	DRP-1851
Ranitidine (As Hydrochloride) 300 mg Film Coated Tablet (Ratidin)	DRP-1851-01
Ranitidine (as Hydrochloride) 25 mg/mL Solution for Injection (IM/IV) (Ameket)	DRP-8324
Ranitidine (As Hydrochloride) / Magnesium Aluminosilicate / Magnesium Aluminum Hydrate / Magnesium Oxide 28.227 mg/125 mg/100 mg/50 mg Film-Coated Tablet (Ranilex)	DR-XY43504
Ranitidine Hydrochloride 25 mg/mL Solution for Injection	DR-XY30531

(Raxide)	
Ranitidine Hydrochloride 150mg Film-Coated Tablet (Raxide)	DR-XY26358
Ranitidine Hydrochloride 300mg Film-Coated Tablet (Raxide)	DR-XY30701

However, for other registered ranitidine products for human use that are yet to submit their testing, the FDA Philippines maintains the following directives:

1. Suspension of all operations (i.e., manufacture, importation, exportation, distribution, offer for sale) of concerned establishments, e.g., Marketing Authorization Holders (MAH), manufacturers, importers, exporters, distributor/sub-distributor, dealing with ranitidine products excluding those in the retail level. Ranitidine products currently available in the retail outlets can still be consumed;
2. Strict utilization of either Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS) or Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) as recommended by the US FDA for every registered ranitidine product showing the analyses, in available batches of both the drug substance/active pharmaceutical ingredient (API) and the finished product, to determine the presence of NDMA;
3. Submission of complete documents including the following:
    a. Certificates of Analysis of API and Finished Product
    b. Analytical Results
    c. Analytical raw data including chromatograms/spectra
    d. Other relevant data
4. Provision of these documents must be done by all affected MAHs/establishments **within thirty (30) calendar days from issuance of this amendment** through submission to both these email addresses: fdac.letters.cdrr@fda.gov.ph and cdrr_postmarketsurveillance@fda.gov.ph containing the subject: Ranitidine-*[Name of MAH/establishment]*. A list of your registered ranitidine products with its registration numbers and the complete address of every API manufacturer/supplier must also be reflected in the body of your e-mail.

Resumption of operations of affected ranitidine products shall depend on the compliance of its MAH and non-submission of required documents shall lead to regulatory action/s without prior notice. Furthermore, the FDA Philippines shall still stringently monitor all ranitidine products under Post-Marketing Surveillance.

Dissemination of the information to all concerned is requested.

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Director General

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