Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration PHILIPPINES

FDA ADVISORY
No. 2022-0419

24 FEB 2022

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

SUBJECT: **UPDATED LIST OF RANITIDINE- CONTAINING PRODUCTS**

The Food and Drug Administration (FDA) hereby advises the concerned licensed drug 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 is updated as follows:

GENERIC NAME, DOSAGE STRENGTH AND FORM	BRAND NAME	REG. NO.
Ranitidine (as hydrochloride) 150 mg Tablet	Contracid	DRP-1237
Ranitidine (as Hydrochloride) 150 mg Tablet	Radine	DR-XY32319
Ranitidine (as hydrochloride) 150 mg Tablet	Ranae	DRP-1237-01
Ranitidine (As Hydrochloride) 150 mg Film Coated Tablet	Ranitein	DRP-1857
Ranitidine (As Hydrochloride) 150 mg Film Coated Tablet	Ratidin	DRP-1857-01
Ranitidine Hydrochloride 150mg Film-Coated Tablet	Raxide	DR-XY26358
Ranitidine 150 mg Film-Coated Tablet	Zilatec	DRP-4651
Ranitidine (as hydrochloride) 300 mg Film-Coated Tablet	Alcera	DRP-4494
Ranitidine (As Hydrochloride) 300 mg Film Coated Tablet	Ranitein	DRP-1851
Ranitidine (As Hydrochloride) 300 mg Film Coated Tablet	Ratidin	DRP-1851-01
Ranitidine Hydrochloride 300mg Film-Coated Tablet	Raxide	DR-XY30701
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)	Aglotac	DRP-6135
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Solution for Injection	Alflux	DRP-7635
Ranitidine Hydrochloride 25 mg/mL Solution for Injection	Ameket	DR-XY28707
Ranitidine (as Hydrochloride) 25 mg/mL Solution for Injection (IM/IV)	Ameket	DRP-8324

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 Solution for Injection (IM/IV)	Apo-tin	DRP-6304
Ranitidine Hydrochloride 50 mg/2 mL Sterile Solution for Injection (IM/IV)	Contracid	DRP-655
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)	Eastidine	DRP-869-01
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) Solution for Injection	Entac	DR-XY29322
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 Solution for Injection (IM/IV)	Hacidac	DRP-869-02
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)	Primudine	DRP-6304-01
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV)	Qualran	DRP-159
Ranitidine (as Hydrochloride) 25 mg/mL Solution for Injection (IM/IV)	Ranidex	DR-XY39911
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV)	Ranipen	DRP-159-09
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection (IM/IV)	Ranistar	DRP-7171-01
Ranitidine (as hydrochloride) 25 mg/mL Solution for Injection	Ranitein	DRP-2017
Ranitidine Hydrochloride 25 mg/mL Solution for Injection	Raxide	DR-XY30531
Ranitidine Hydrochloride 25mg/mL Solution for Injection (IM/IV)	Raxidine	DR-XY39368
Ranitidine Hydrochloride 25 mg/mL Solution for Injection (IM/IV)	Siutec	DR-XY31808
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 Solution for Injection (IM/IV)	Westran	DRP-159-07

Ranitidine Hydrochloride 25 mg/mL (50 mg /2 mL) Solution for Injection (IM / IV)	Zantol	DR-XY40614
Ranitidine (as hydrochloride) 25 mg/mL (50 mg/2 mL) Sterile Solution for Injection (IM/IV)	Zantricid	DRP-159-04
Ranitidine Hydrochloride + Tripotassium Bismuth Dicitrate + Sucralfate 84 mg/100 mg/300 mg Film-Coated Tablet	Albis	DR-XY44001
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

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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