



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY
No. **2016-079-A**

21 JUL 2016

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Use of the Counterfeit Albumin (Human) (Albonorm 20%) 20 g / 100 mL and (Albonorm 25%) 25 g / 100 mL Solution

The Food and Drug Administration (FDA) advises the public against the use of the counterfeit Albumin (Human) (Albonorm 20%) 20 g / 100 mL and (Albonorm 25%) 25 g / 100 mL Solution.



Figure 1. Counterfeit Albumin (Human) (Albonorm 20%) 20 g / 100 mL Solution.

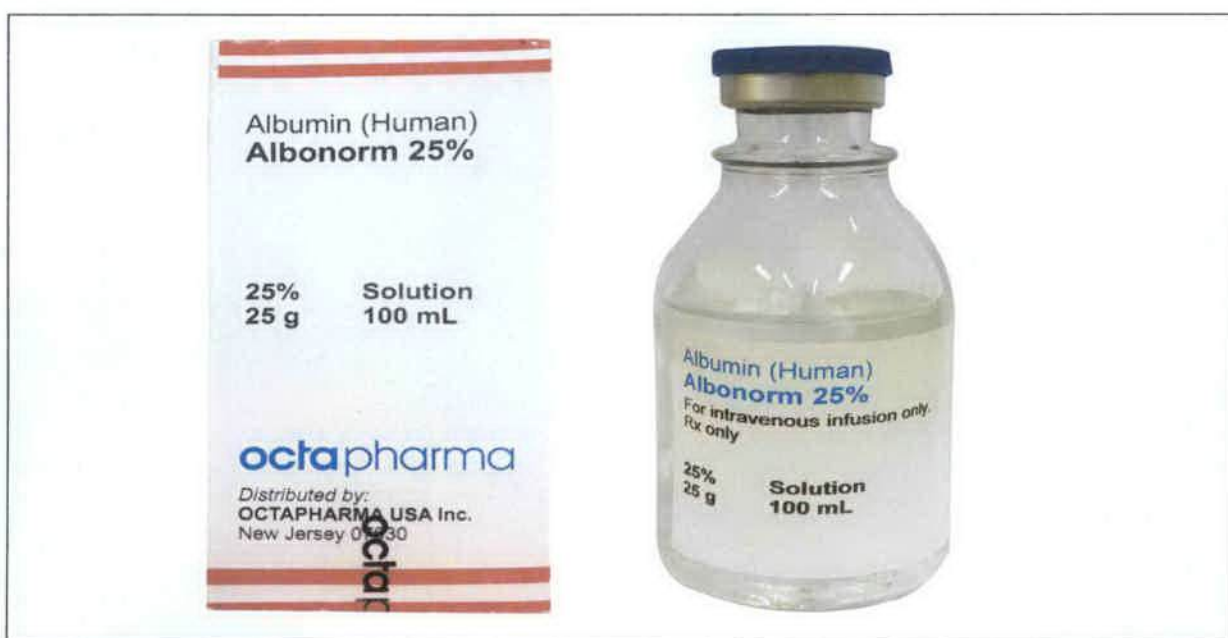


Figure 2. Counterfeit Albumin (Human) (Albonorm 25%) 25 g / 100 mL Solution.



Medlink Marketing, the Marketing Authorization Holder of Human Albumin (Albunorm) 20% and 25% Solution, has confirmed that the above-mentioned products are counterfeit. Octapharma, being reflected in the counterfeit product as the Distributor, is the manufacturer of the authentic product. The counterfeit products carry the brand name "Albonorm" while the authentic product is "Albunorm" (Please note the difference in the fourth letter of the name).

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned counterfeit drug product. This poses 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, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs.

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 drug product. Anyone found selling the said drug product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this drug product is not sold or offered for sale in their localities or area of jurisdiction.

Consumers are advised to purchase their medications only from FDA-licensed establishments. 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. 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), please e-mail us via adr@fda.gov.ph.

Dissemination of the information to all concerned is requested.


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