

December 20, 2023

NOTICE TO 340B COVERED ENTITIES REGARDING UTILIZATION OF Albutein® Vial & Albutein® FlexBag (albumin [human] U.S.P.).

Grifols began introducing Albutein® FlexBag containers in April 2021. Currently, Albutein is available in the United States in both Vials and FlexBag containers. While there are new NDCs for the FlexBag containers, there is no change to the product (drug, dose, formulation, or volume) or price, as represented by the corresponding existing vial NDCs in the US.

The tables below reflect the NDCs for Albutein® Vials and Albutein® FlexBag that have one or more corresponding equivalents. Because these FlexBag NDCs (5% and 25%) are, in fact, the same product (drug, dose, formulation, and volume) with the same price as the Vial NDCs (5% and 25%), Grifols believes that a covered entity utilizing a 340B inventory replenishment model may use and count accumulations of these NDCs (whether Vials and FlexBags 5% or Vials and FlexBags 25%) toward replenishment of equal quantities of the corresponding FlexBag NDCs (see below table). Furthermore, replenishment may also take place between corresponding Albutein FlexBag NDCs by strength.

Albutein 5%			
Vials		FlexBags	
NDC	Product Description	NDC	Product Description
68516-5214-01	Albutein 5% 250mL	68516-5214-09 68516-5218-04	Albutein FlexBag 5% 12.5g 250mL 4pk Albutein FlexBag 5% 12.5g 250mL 4pk
68516-5214-02	Albutein 5% 500mL	68516-5214-00 68516-5219-02	Albutein FlexBag 5% 25g 500mL 2pk Albutein FlexBag 5% 25g 500mL 2pk

4 vials of 68516-5214-01 equal 1 package of 68516-5214-09 or 68516-5218-04.

2 vials of 68516-5214-02 equal 1 package of 68516-5214-00 or 68516-5219-02.

Albutein 25%			
Vials		FlexBags	
NDC	Product Description	NDC	Product Description
68516-5216-01	Albutein 25% 50mL	68516-5216-07 68516-5216-09	Albutein FlexBag 25% 12.5g 50mL 5pk Albutein FlexBag 25% 12.5g 50mL 5pk
68516-5216-02	Albutein 25% 100mL	68516-5216-08 68516-5216-00	Albutein FlexBag 25% 25g 100mL 5pk Albutein FlexBag 25% 25g 100mL 5pk

5 vials of 68516-5216-01 equal 1 package of 68516-5216-07 or 68516-5216-09.

5 vials of 68516-5216-02 equal 1 package of 68516-5216-00 or 68516-5219-08.



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