

IMPORTANT NOTIFICATION: Labeling and packaging updates for ALPHANATE

Grifols is dedicated to ensuring that healthcare professionals, pharmacies, and distributors have the information to manage ALPHANATE safely and effectively. As part of our ongoing commitment to improving product identification and accessibility, we have updated the labeling and packaging of ALPHANATE.

This communication provides a detailed overview of these changes, including a side-by-side comparison of the old and new color schemes, essential clarifications regarding accessibility, and the timeline for the transition to the new packaging.

KEY UPDATES TO ALPHANATE STRENGTH LABELS

1 Updated color scheme for strength identification

- The color scheme has been revised to improve clarity
- Notable changes:**
 - The **250 IU FVIII range**, previously represented by gray, is now a deeper shade of gray
 - The **500 IU FVIII range**, previously represented by blue, is now green
 - The **1000 IU FVIII range**, previously represented by red, is now blue
 - The **1500 IU FVIII range**, previously represented by black, is now orange
 - The **2000 IU FVIII range**, previously represented by green, is now magenta
- The shade of blue for the 1000 IU FVIII range is distinct from the shade of blue previously used for the 500 IU FVIII range
- Please note these differences, as you may encounter existing inventory with previous labeling while new labeling is being distributed

2 Comparison of previous vs. updated colors

- The table below outlines the specific updates for each strength:

Outer NDCs (10-digit)	Previous strength colors	New strength colors
68516-4611-1 / 68516-4616-1	250 IU FVIII Range	250 IU FVIII Range
68516-4612-1 / 68516-4617-1	500 IU FVIII Range	500 IU FVIII Range
68516-4613-2 / 68516-4618-2	1000 IU FVIII Range	1000 IU FVIII Range
68516-4614-2 / 68516-4619-2	1500 IU FVIII Range	1500 IU FVIII Range
68516-4615-2 / 68516-4620-2	2000 IU FVIII Range	2000 IU FVIII Range

3 Accessibility considerations for individuals with color vision deficiency (CVD)

- To support users with CVD, the new labels prominently display text-based strength identifiers in addition to the color coding
- We recommend always confirming the strength presented on the label

4 Transition timeline for previous labels

- The last lot of ALPHANATE packaged with the previous labeling and strength colors will expire on March 13, 2026. Please refer to the expiration date printed on the carton for each package size. You may encounter both old and new packaging in the field until this date

Thank you for your continued trust in Grifols and ALPHANATE. Should you have any questions, please contact Grifols Customer Service at: customer.service@grifols.com or **1-800-243-4153**.