

IMPORTANT NOTIFICATION: Labeling and packaging updates for AlphaNine SD

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

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 ALPHANINE SD STRENGTH LABELS

1 Updated color scheme for strength identification

- The color scheme has been revised to improve clarity
- Notable changes:**
  - The **500 IU FIX range**, previously represented by blue, is now gray
  - The **1000 IU FIX range**, previously represented by red, is now green
  - The **1500 IU FIX range**, previously represented by black, is now a lighter shade of blue
- The shade of blue for the 1500 IU FIX range is distinct from the shade of blue previously used for the 500 IU FIX 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
68516-3610-2 / 68516-3607-2	500 IU FIX Range	500 IU FIX Range
68516-3611-2 / 68516-3608-2	1000 IU FIX Range	1000 IU FIX Range
68516-3612-2 / 68516-3609-2	1500 IU FIX Range	1500 IU FIX 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 AlphaNine SD packaged with the previous labeling and strength colors will expire on March 27, 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 AlphaNine SD. Should you have any questions, please contact Grifols Customer Service at: [customer.service@grifols.com](mailto:customer.service@grifols.com) or 1-800-243-4153.