



BAVARIAN NORDIC

CDC/DDID/NCEZID/DPEI

14-Jun-2022

To whom it may concern,

For operational flexibility, drug product may be shipped either frozen at -20°C (-4°F) or refrigerated at $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$) during an event depending on freezer capacity at the receiving site(s). Upon receipt the vaccine can be stored as follows:

If vaccine is shipped frozen at -20°C and requires storage before use, maintain:

- Frozen (-20°C), if freezer capacity is available,
OR
- Refrigerated ($2-8^{\circ}\text{C}$). Do not refreeze.

If vaccine is shipped at $2-8^{\circ}\text{C}$ and requires storage before use, maintain:

- Refrigerated at $2-8^{\circ}\text{C}$. Do not refreeze.

Unopened vials of drug product may be stored at $2-8^{\circ}\text{C}$ up to 8 weeks from thawing. This information has been provided by the vaccine manufacturer based on available supportive stability data.

Please be aware that this differs from the storage and use by period of 12 hours once thawed that is found in the JYNNEOS package insert (Sections 2.2. Preparation and Administration and 16.2 Storage Conditions).

If stored frozen (-20°C), the vaccine should be used within the printed expiration date on the carton. Please note that the expiration date is not shown on the individual vial.”

Best Regards,


Snr. Director CMC Regulatory Affairs
Bavarian Nordic A/S

DocuSigned by:


