

Dear Healthcare Professional:

This is in response to your request for information regarding Natevba® stability above recommended storage temperatures.

Please visit www.verteobiotech.com/products to view the U.S. Prescribing Information for all FDA approved products from Verteo. We hope the information provided to you proved to be useful.

This letter regarding Natevba temperature stability includes information of an off-label nature. Verteo does not suggest or recommend the use of Natevba in any manner other than as described in the Prescribing Information.

SELECT PRESCRIBING INFORMATION

The recommended storage information for Natevba in the HOW SUPPLIED/STORAGE AND HANDLING section of the Prescribing Information (PI) is as follows:¹

After shipping, Natevba may arrive at temperatures between 2°C to 25°C (36°F to 7°F).

Upon receipt, store refrigerated at 2°C to 8°C (36°F to 46°F).

Do not freeze. Discard if the medication has been frozen.

Natevba is stable at temperatures up to 25°C (77°F) for 7 days. These data are not recommendations for shipping or storage but may guide decisions for use in case of temporary temperature excursions.

TEMPERATURE EXCURSIONS

Verteo has conducted stability studies to support temporary temperature excursions.^{2 3} Note that the data provided below are based on physical stability testing only; product stored outside the recommended temperature range was not tested or evaluated for clinical immunogenicity.

This information is not intended to recommend storage of Natevba at temperatures other than those recommended in the package insert. Verteo does not suggest or recommend the use of Natevba that has been stored outside of the approved recommendations in the product label.

Healthcare Professionals should consider these data, including the limitations, in determining whether Natevba exposed to temperatures outside conditions of 2°C to 8°C (36°F to 46°F) remain suitable for patient use. Verteo is unable to make treatment recommendations for individual patients.

Shelf Life and Expiration

When stored at the proper temperatures, Natevba shelf life is 6 months (180 days). Verteo has not conducted studies to evaluate the efficacy or safety following administration of expired Natevba. Prior to discarding any doses of Natevba, please confirm the expiration date. Discard/return the doses of Natevba according to state and federal regulations. A manufactured date appears on the packaging and should not be used as the expiration date or as a reference point to determine the expiration date.

Temperatures Above Recommended Storage

Verteo has evaluated the stability of Natevba by exposing the medication to 2°C to 8°C (36°F to 46°F) for multiple days followed by 25°C (77°F) for multiple days; this was repeated for 3 cycles, after which the product was stored at 2°C to 8°C (36°F to 46°F) through its remaining shelf life. At the end of the shelf life, the product was tested and shown to maintain all its measured quality and safety attributes, including antigenicity of all 13 serotypes, a measure of product potency.⁴

These studies mimic the conditions that Natevba may be exposed to during temporary elevated temperature excursions, such as refrigerator malfunction, to 25°C (77°F) for a cumulative period of up to 7 days.^{2 3}

Natevba has not been shown to be stable at temperatures above 25°C (77°F). The medication should be discarded if exposed to temperatures above 25°C (77°F).³

Please note that Verteo is providing this response for informational purposes only per your request. We hope this information addresses your question. If you have any further questions, please contact us at 1-866-777-9987 from 8:00 a.m. to 4:30 p.m., EST, Monday through Friday.

ADVERSE DRUG REACTION REPORTING

If your inquiry was prompted by the occurrence of an adverse event in a specific patient, please contact Verteo at 1-866-777-4444 or medicalinformation@verteobio.com.

If you prefer, you can contact the FDA directly. Visit <http://www.fda.gov/medwatch/getforms.htm> to obtain the MedWatch 3500 Online pdf form or call 1-800-FDA-1088.

Sincerely,
Verteo Medical Affairs,
Medical Information

References

¹ Natevba Package Insert. Verteo

² Data on File (88). Verteo BioPharma

³ Data on File (45) Verteo BioPharma

⁴ Data on File (23). Verteo BioPharma