

PREZISTA® (darunavir) Oral Suspension

Stability of PREZISTA Oral Suspension – Shipping and Storage Temperature Excursions

SUMMARY

- PREZISTA Oral Suspension may be shipped from the manufacturer in a cooler with gel packs to maintain shipping temperature requirements.
 - Once received, the Oral Suspension should be stored at room temperature (25°C; 77°F), with excursions permitted between 15°C to 30°C (59°-86°F).¹
- Janssen cannot recommend any practices, procedures, or storage conditions that deviate from the product labeling and are not approved by regulatory authorities.

SHIPPING TEMPERATURE DATA

- PREZISTA Oral Suspension has shipping temperature ranges noted in [Table: Shipping Temperature Ranges](#) that are more exhaustive than that of the storage requirements listed in the prescribing information.²
 - Janssen may use qualified passive shipping solutions (e.g. coolers) to ensure that the product maintains the appropriate shipping temperature range during shipping to customers. These coolers have components (e.g. gel packs) that may be cold. This is expected as some of the gel packs are required to be cold to ensure that the appropriate shipping temperature ranges are maintained.
 - The temperature confirmation of the cooler upon arrival may be outside of the storage specific requirements listed in the prescribing information; however, the product is fit for use as long as the cooler temperature was within the shipping temperature ranges.
- Upon receipt, ensure that the product is stored at 25°C (77°F), with excursions permitted between 15° to 30°C (59°-86°F).

Table: Shipping Temperature Ranges²

Product	Shipping Temperature Ranges
PREZISTA Oral Suspension	2°C to 35°C

STORAGE CONDITIONS - ADDITIONAL TEMPERATURE EXCURSION DATA

- Off-label data are available for situations outside of recommended storage requirements. This information is provided in response to your unsolicited request.
 - These data were collected in strictly controlled environments. All tested product is stored in sealed containers. It is not possible to predict and design studies that reflect every combination or duration of temperatures that a customer's product may encounter. Therefore, caution is recommended in assessing the effects of specific excursions on a product.
- Stability studies were conducted with PREZISTA Oral Suspension to provide the acceptable limits for temperature excursions outside of the recommended storage condition of 25°C.
- Based on the stability data, PREZISTA Oral Suspension was not adversely affected when exposed to conditions within the acceptable limits as noted in [Table: Proven Limits for Temperature Excursions](#).

Table: Proven Limits for Temperature Excursions^{2, 3}

Product	Proven Temperature Ranges
PREZISTA Oral Suspension	5°C to 15°C – 3 months 30°C to 40°C – 10 days

REFERENCES

1. PREZISTA (darunavir) [Prescribing Information]. Titusville, NJ: Janssen Therapeutics, Division of Janssen Products, LP; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PREZISTA-pi.pdf>.
2. Data on File. Proven Temperature Ranges for JSC Drug Products. TV-TEC-102593. 2023.
3. Data on File. Janssen R&D, LLC. Stability statement: JNJ-25875382-AAA/R319064/darunavir/TMC114-F052 eq. 100mg/ml oral suspension. TV-TEC-107381.