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For further information regarding Indication, **Boxed WARNING** and other Important Safety Information for NUPLAZID, please click here: <u>Prescribing Information</u>.

## **ACADIA**

## NUPLAZID<sup>®</sup> (pimavanserin) Temperature Excursion Information

This letter is provided in response to your specific request for information regarding temperature excursions with NUPLAZID.

Per the product labeling for NUPLAZID, the recommended storage conditions are  $20^{\circ}$ C to  $25^{\circ}$ C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F).<sup>1</sup>

Please refer to the United States Pharmacopeia (USP) definition of controlled room temperature to inform your medical judgment on the decision to use the product, where the following conditions also apply:<sup>2</sup>

- Mean kinetic temperature not to exceed  $25^{\circ}$  (77° F).
- Excursions between 15° and 30° (59° and 86° F) that are experienced in pharmacies, hospitals, and warehouses, and during shipping are allowed.
- Provided the mean kinetic temperature does not exceed 25° (77° F), transient spikes up to 40° (104° F) are permitted as long as they do not exceed 24 h.
- Spikes above 40° (104° F) may be permitted only if the manufacturer so instructs.

## References

- 1. NUPLAZID<sup>®</sup> (pimavanserin) [package insert]. San Diego, CA. Acadia Pharmaceuticals Inc. [Link]
- 2. The United States Pharmacopeial Convention. Revision Bulletin: May 1, 2017. [Link].