VELETRI® (epoprostenol)
VELETRI - Shelf Life of Lyophilized Powder After Temperature Excursions

CLINICAL DATA

The stability of unreconstituted VELETRI for injection 0.5 mg and 1.5 mg vials was investigated at different excursion temperatures at various time points.[1] The effect of product quality was measured in terms of the appearance, constituted solution pH, moisture, particulate matter, content, related substances, bacterial endotoxins, and sterility. The excursion temperatures and total maximum duration of exposure to maintain stability of unreconstituted VELETRI for injection based on the results of these investigations can be found in Table: Total Maximum Duration of Exposure of Unreconstituted VELETRI for Injection 0.5 mg and 1.5 mg Vials.[1]

Total Maximum Duration of Exposure of Unreconstituted VELETRI for Injection 0.5 mg and 1.5 mg Vials[1]

Temperature	Total Maximum Duration of Exposure
≥−20°C to <2°C	6 days
>30°C to ≤40°C	7 days
>40°C to ≤60°C	8 hours

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 29 March 2024.

REFERENCES

1. Data on File. Epoprostenol. Temperature Stability Profile Assessment. Janssen Scientific Affairs, LLC. FRM-100407; 2021.