

## PROCRIT® (epoetin alfa) PROCRIT - Shipping Stability

### SUMMARY

- Store at 36°F to 46°F (2°C to 8°C). Do not freeze.<sup>1</sup>
- Do not shake. Do not use PROCRIT that has been shaken or frozen.<sup>1</sup>
- The manufacturer cannot recommend any shipping practices that deviate from product labeling and are not approved by the regulatory agencies.<sup>2</sup> Data regarding stability during shipping and the FREEZEMarker® indicator are provided below.

### PRODUCT LABELING

Please refer to the following sections of the full Prescribing Information that are relevant to your inquiry: DOSAGE AND ADMINISTRATION, DESCRIPTION, PREPARATION AND ADMINISTRATION, and HOW SUPPLIED/STORAGE AND HANDLING.<sup>1</sup>

### CLINICAL DATA

#### Stability During Shipping

- While PROCRIT is a stable biologic product, care should be taken to ensure that temperature control is maintained while transporting the product. Store PROCRIT under refrigerated conditions at a temperature of 36°F to 46°F (2°C to 8°C).<sup>2</sup>
- The manufacturer does not have stability data to support the use of PROCRIT multiple-dose vials exposed to temperatures below 2°C (36°F). PROCRIT multiple-dose vials exposed to temperatures below the recommended temperature range of 2°C to 8°C (36°F to 46°F) should not be used.<sup>2</sup>

#### PROCRIT Multiple-dose Vial: FREEZEMarker indicator<sup>3</sup>

- A temperature indicator called a 'FREEZEMarker' is contained within the carton of PROCRIT multiple-dose vials and will be triggered when exposed to freezing temperatures. PROCRIT should be shipped and stored in its original packaging. The FREEZEMarker single-use indicator will irreversibly change from green to white when the product has been exposed to freezing temperatures. It is only used to determine whether product has been exposed to freezing temperatures.
  - The product has not been exposed to freezing temperatures and is okay to use if the following is displayed on the FREEZEMarker indicator:
    - If there is a white check mark clearly displayed on a green circle background.
  - Do not use the product if the following is displayed on the FREEZEMarker indicator:
    - If the indicator inside the circle is partially or completely changed to white, opaque, or cloudy.
    - If the FREEZEMarker indicator has been triggered, contact the Medical Information Department at 1800-JANSSEN (1-800-526-7736) to report the event.

### LITERATURE SEARCH

A literature search of MEDLINE® (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 14 August 2023.

### REFERENCES

1. PROCRIT (epoetin alfa) [Prescribing Information]. Horsham, PA: Janssen Products, LP; <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/PROCRIT-pi.pdf>.
2. Data on File. Epoetin alfa Stability at Freezing Temperatures; correspondence from Amgen. 2023.

3. Freezemarker Indicators. Temptime Corporation. Available at: <https://www.zebra.com/us/en/products/environmental-sensors/ready-to-use-indicators/freeze-indicators.html>. Accessed August 13, 2023.