

**PROCRIT® (epoetin alfa)  
10,000 Units/mL and 20,000 Units/mL Multiple-Dose Vials  
FREEZEmarker® Indicator**

## **SUMMARY**

The manufacturer cannot recommend any practices, procedures, or storage conditions that deviate from product labeling for epoetin alfa.<sup>1</sup> Data regarding the epoetin alfa multiple-dose vial, specifically freezing stability and the FREEZEmarker® indicator, are provided below.

## **PRODUCT LABELING**

PROCRIT is formulated as a sterile, colorless, preservative-free liquid with each single-dose vial containing 2000, 3000, 4000, 10,000 or 40,000 Units (U) of epoetin alfa per 1 mL. PROCRIT is also available in multiple-dose vials of 20,000 U (10,000 U/mL in a 2 mL vial, 20,000 U/mL in a 1 mL vial) that contain benzyl alcohol as a preservative.<sup>2</sup>

Please note the following as stated in the HOW SUPPLIED/STORAGE AND HANDLING and PREPARATION AND ADMINISTRATION sections of the PROCRIT Prescribing Information<sup>2</sup>:

- Store at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store PROCRIT vials in the original carton until use to protect from light.
- Do not shake. Do not use PROCRIT that has been shaken or frozen.
- Protect vials from light.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use any vials exhibiting particulate matter or discoloration.
- Discard unused portions of PROCRIT in preservative-free vials. Do not re-enter preservative-free vials.
- Store unused portions of PROCRIT in multiple-dose vials at 36°F to 46°F (2°C to 8°C). Discard 21 days after initial entry
- Do not dilute. Do not mix with other drug solutions except for admixing as described below:
  - Preservative-free PROCRIT from single-dose vials may be admixed in a syringe with bacteriostatic 0.9% sodium chloride injection, USP, with benzyl alcohol 0.9% (bacteriostatic saline) in a 1:1 ratio using aseptic technique at the time of administration.
  - Do not mix PROCRIT with bacteriostatic saline when administering to pregnant women, lactating women, neonates, and infants (see Use in Specific Populations).
- PROCRIT from multiple-dose vials contains benzyl alcohol and is contraindicated in neonates, infants, pregnant women, and lactating women (see Use in Specific Populations).

## **STABILITY AND EXCURSION DATA**

### **Freezing Stability<sup>1</sup>**

#### ***Preserved, multiple-dose vials: 20,000 U/2mL and 20,000 U/mL***

- The manufacturer does not have stability data to support the use of epoetin alfa multiple-dose vials exposed to temperatures below 2°C (36°F). Epoetin alfa 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. A temperature indicator called a 'FREEZEmarker' is contained within the carton and will be triggered when exposed to freezing temperatures. Epoetin alfa should be shipped and stored in its original packaging.

## Multiple-dose Vial: FREEZEmarker Indicator<sup>3</sup>

### **Preserved, multiple-dose vials: 20,000 U/2mL and 20,000 U/mL**

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 FREEZEmarker is a single-use freeze indicator that provides an easy-to-read, irreversible visual signal when a freeze event at or below the response temperature occurs. The green circle and white checkmark are visible in the indication window at temperatures above the response temperature. When exposed to temperatures at or below the response temperature, the green circle and white checkmark will turn partially or completely white (opaque/cloudy), showing that a temperature excursion has occurred and endpoint has been reached.

- If the FREEZEmarker indicator has been triggered, contact the Medical Information Department at 1-800-JANSSEN (1-800-526-7736) to report the event.

## LITERATURE SEARCH

A literature search of Ovid MEDLINE®, Embase, BIOSIS Previews®, and Derwent Drug File databases (and/or other resources, including internal/external databases) was conducted on 13 August 2023.

## REFERENCES

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