



**Date:** 01 February 2012  
**To:** Pharmacy Directors and Pharmacy Staff  
**Urgent:** Bag Compatibility for Caldolor® (ibuprofen) Injection 800 mg (NDC# 66220-287-08)

Ongoing research indicates that, under certain circumstances including refrigeration and freezing, a precipitate may form when Caldolor (ibuprofen) Injection is diluted in B. Braun Excel bags. This precipitate was not observed when using Baxter Viaflex 250mL saline bags.

Therefore, it is recommended that **Baxter Viaflex 250mL bags** and NOT B. Braun Excel bags be used when diluting Caldolor prior to intravenous infusion.

Caldolor must be diluted prior to intravenous infusion. Appropriate diluents include 0.9% Sodium Chloride Injection USP (normal saline), 5% Dextrose Injection USP (D5W), or Lactated Ringers Solution. Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. If visibly opaque particles, discoloration or other foreign particulates are observed, the solution should not be used.

Caldolor is indicated in adults for the management of mild to moderate pain and the management of moderate to severe pain as an adjunct to opioid analgesics. Caldolor is indicated for the reduction of fever in adults.

There is no need to refrigerate Caldolor when diluted.

**WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS**

Cardiovascular Risk

- Non-steroidal anti-inflammatory drugs (NSAIDs) may increase the risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
- Caldolor is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

- NSAIDs increase the risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

For questions concerning Caldolor or to report suspected adverse reactions, contact Cumberland at 1-877-484-2700.

Thank you,

A handwritten signature in black ink that reads "Amy D. Rock".

Amy D. Rock, PhD  
Senior Director, Regulatory & Scientific Affairs

**CUMBERLAND PHARMACEUTICALS INC.**