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Extraneal (2019-03-22) Report a Concern (http://www.healthycan adians.gc.ca/reportsignalez/indexeng.php) Starting date: March 22, 2019 Type of communication: Drug Recall Subcategory: Drugs Hazard classification: Type I Source of recall: Health Canada Issue: Product Safety Audience: General Public, Healthcare Professionals, Hospitals Identification number: RA-69416 Depth of distribution Reason Affected products

Recalled Products

Extraneal solution

Reason

Active pharmaceutical ingredient (Icodextrin) used in affected lots contains elevated levels of sodium hypochlorite.

Depth of distribution

Healtcare Establishments, End users

Affected products

Extraneal solution

DIN, NPN, DIN-HIM

DIN 02240806

Dosage form

Solution

Strength

Calcium chloride 257 mg/L Icodextrin 75 g/L Magnesium chloride 51 mg/L Sodium chloride 5.35 g/L Sodium lactate 4.48 g/L

Lot or serial number

W9B28T0, W9C05T1

Companies

Recalling Firm

Baxter Corporation 7125 Mississauga Road Mississauga L5N 0C2 Ontario CANADA Marketing Authorization Holder Baxter Corporation

7125 Mississauga Road Mississauga L5N 0C2 Ontario CANADA

Date modified: 2019-03-25