Taro Pharmaceuticals Inc. Issues Voluntary Type I Recall of Taro-Zoledronic Acid Injection, 5 mg/100 mL, 100 mL Vial Due to Particulate Matter Over Specified Requirements

August 11, 2022

BRAMPTON, Ontario--(BUSINESS WIRE)--Aug. 11, 2022-- Taro Pharmaceuticals Inc. has initiated a voluntary Type 1 recall to the patient level on six (6) lots of Taro-Zoledronic Acid Injection, 5 mg/100 mL in 100 mL vials. The reason for the recall is that product from these lots may contain particulate matter over the specified requirements. This recall is being conducted with the knowledge of Health Canada.

The presence of foreign particulate matter in vials of the affected lots could potentially cause unintended adverse events. Taro has received **no reports of serious adverse events** associated with this product.

The impacted lots are listed below.

Sr. No	Batch No.	Expiry. Date
1	JKX1910A	April-2023
2	JKX4318A	Aug-2023
3	JKX5541A	Nov-2023
4	HAC2371A	Jun-2024
5	HAC4421A	Nov-2024
6	HAD0156A	Jan-2025

Taro-Zoledronic Acid Injection, 5 mg/100 mL is used to increase bone mineral density, to treat and prevent osteoporosis as well as to treat Paget's disease (a condition that causes bone deformities).

Consumers in possession of Taro-Zoledronic Acid Injection should check to see if the product is one of the six (6) referenced lots listed above and, if so, return the drug to their pharmacy.

To report a suspected adverse event related to Taro-Zoledronic Acid Injection, please contact Taro's Medication Information line at 1-866-877-5180 or by email at PVCanada@taro.com.

Patients may also report any suspected adverse reaction associated with the use of health products to Health Canada by:

- Online at www.healthcanada.gc.ca/medeffect
- Via telephone at 1-866-234-2345
- In writing by completing a Canada Vigilance Reporting Form and
  - Fax at 1-866-678-6789, or
  - Via Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Forms and the adverse reactions reporting guidelines are available on the MedEffect Canada Web site at www.healthcanada.gc.ca/medeffect.

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COMPANY CONTACT
William J. Coote
VP, CFO
(914) 345-9001
William.Coote@taro.com

CONSUMER CONTACT
Taro Pharmaceuticals Inc.
Medical Information
1-866-877-5180
PVCanada@taro.com

Source: Taro Pharmaceuticals Inc.