



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## **URGENT MEDICINE RECALL\***

LEVEL: Retail

CLASS: Class II

REFERENCE: RC-2020-RN-00810-1

DATE AGREED: 4/09/2020

**PRODUCT:** **Various Arrotex bufexamac-containing topical products.**

All Batches

AUSTR: 230401 - APOHEALTH First Aid Cream tube

AUSTR: 260392 - BLOOMS THE CHEMIST First Aid Cream tube

AUSTR: 145050 - CHEMISTS' OWN Antiseptic Plus Cream tube

**SPONSOR:** Apotex Pty Ltd

**PHONE:** 1800 276 839 - Arrotex Customer Service

**REASON:** Arrotex Pharmaceuticals Pty Ltd (Arrotex) has initiated a retail level recall of Various bufexamac-containing topical products due to an identified low risk of serious skin reactions, following a recent TGA review. There have been rare reports of serious skin reactions following use of bufexamac, including generalised acute contact dermatitis, erythema multiforme-like reactions and acute generalised exanthematous pustulosis; when severe, these conditions can lead to scarring, a need for skin grafts and permanent disability.

**PROPOSED CUSTOMER ACTIONS:** **WHOLESALEERS:**  
Wholesalers are advised to inspect their stocks on hand for the impacted products and quarantine all impacted product to prevent further use.

**RETAILERS:**  
Retailers are advised to inspect their stocks on hand for the impacted products and quarantine all impacted product to prevent further use. Retailers are advised to contact their Wholesaler to arrange for the return of the impacted stock.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 2381 retail pharmacies nationally

Product export status: Unknown

This issue was first identified by the Sponsor

\*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>