



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

## **URGENT MEDICINE RECALL\***

LEVEL: Retail

CLASS: Class II

REFERENCE: RC-2020-RN-00754-1

DATE AGREED: 4/09/2020

**PRODUCT: Various Cipla bufexamac-containing topical products**

All Batches

AUSTR: 136256 - PHARMACY CHOICE ANTISEPTIC CREAM tube  
AUSTR: 193197 - PHARMACY ACTION ANTISEPTIC CREAM tube  
AUSTR: 225323 - AMCAL FIRST AID CREAM tube  
AUSTR: 275578 - PRICELINE PHARMACY FIRST AID CREAM tube  
AUSTR: 275579 - PHARMACY HEALTH FIRST AID CREAM tube  
AUSTR: 308966 - TERRYWHITE CHEMMART FIRST AID CREAM tube

**SPONSOR:** Cipla Australia Pty Ltd

**PHONE:** 03 9696 4413 - Cipla Australia Customer Service

**REASON:** Cipla Australia Pty Ltd 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:** WHOLESALERS:  
Wholesalers are advised to inspect your stocks on hand for the impacted products and quarantine all impacted product to prevent further use.

RETAILERS:  
Retailers are advised to inspect your stocks on hand for the impacted products and quarantine all impacted product to prevent further use.  
Retailers are advised to contact your 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: 4 distributors in VIC

Product export status: N/A

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>