



Australian Government

Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class I

REFERENCE: RC-2019-RN-01122-1

DATE AGREED: 29/07/2019

PRODUCT: ENDONE oxycodone hydrochloride 5mg tablet blister pack

Batch Number: CW612

Expiry: Nov 2020

AUST R: 14945

SPONSOR: Aspen Pharma Pty Ltd

PHONE: 1300 659 656 - Aspen Medical Information

REASON: A single report has been received from a consumer in South Australia indicating that a strip of 30mg Anamorph tablets was allegedly present in a box of 5mg Endone, post dispensing.

The Anamorph tablets are approximately four times the Endone equivalent dose, so there is a theoretical potential for overdose, particularly if taken by an opioid naïve patient.

This action supersedes the quarantine notice issued 26 July 2019.

PROPOSED CUSTOMER ACTIONS: This action supersedes the retail level quarantine notice issued 26 July 2019.

Actions for Pharmacists:

Pharmacists are requested to visually inspect the blisters in Endone boxes (batch CW612), prior to dispensing the tablets to patients; and

Actions for Consumers:

Prior to use, Patients are requested to visually inspect the blisters in the boxes to verify both blister strips are Endone tablets.

In the event customers identify a blister with 'Anamorph' printed on the back, or any other anomaly, do not use tablets from that strip.

Return any incorrect tablets to the place of purchase.

Further information is available on the TGA website at:

<https://www.tga.gov.au/alert/endone-5-mg-tablets>

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreement date given above.

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: Retail Pharmacies nationally

Product export status: Unknown

This issue was first identified by a consumer in SA and reported to the TGA online, via a [Medicine Problem Report Form](#).

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