Endone 5 mg tablets

Product defect correction – potential for incorrect medicine in the pack

30 July 2019

Consumers and health professionals are advised that Aspen Pharma, in consultation with the TGA, is undertaking a product defect correction for one batch of Endone 5 mg tablets (batch number CW612, expiry November 2020).

A single pack of Endone 5 mg tablets in South Australia has been found to contain a blister sheet of Anamorph 30 mg tablets.

While the product names were correctly printed on the back of the blister sheet, the tablets and the blisters are a similar size, shape and colour, which increases the risk of inadvertently taking the wrong medicine.

Both Endone 5 mg tablets (containing oxycodone) and Anamorph 30 mg tablets (containing morphine) are strong, prescription pain medication. However, Anamorph 30 mg is a stronger dose (approximately four times the morphine equivalent dose of Endone) and could result in overdose and serious health risks if taken inadvertently.

Before taking any tablets from the affected batch of Endone 5 mg, patients should visually inspect blister sheets to ensure they contain the correct medicine.

As a further precautionary measure, pharmacists are also being asked to visually inspect the contents of packets of Endone 5 mg tablets from the affected batch to ensure they are correct before dispensing.

Information for consumers

If you or someone you provide care for is taking Endone 5 mg tablets from the affected batch (batch number CW612, expiry November 2020), visually inspect the blister sheets before taking it. If you have a blister sheet with 'Anamorph' printed on the back, or anything other than 'Endone 5 mg', do not take those tablets. Return any incorrect tablets to your pharmacy.

If you have any questions or concerns regarding this issue, talk to your health professional.

Information for health professionals

Please be aware of this issue and advise patients accordingly if they return incorrect tablets or seek advice.

The quarantine placed on Endone 5 mg tablets from batch number CW612 on Friday 26 July 2019 has been lifted.

If any incorrect blister sheets are found in packs of Endone 5 mg tablets, or any other product, you should inform the sponsor and follow all relevant dispensing guidelines and in accordance with your jurisdictional poisons legislation.

If you have any questions or concerns about this issue, contact Aspen Pharma by phone on 1300 659 646 or email at medical@aspenpharmacare.com.au.

Reporting problems

Consumers and health professionals are encouraged to <u>report problems with medicines or vaccines</u>. Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medicine or vaccine.

- Category:Alert/Advisory
- Tags:recalls
- URL:https://www.tga.gov.au/node/874876

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