



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

## **URGENT PRODUCT DEFECT CORRECTION\***

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2019-RN-00192-1

DATE AGREED: 12/02/2019

**PRODUCT:** **JURNISTA hydromorphone hydrochloride 8 mg prolonged release  
14 tablet blister pack**

Product Number: AN412056

Batch Number: IALS400

AUST R: 141508

**SPONSOR:** Janssen-Cilag Pty Ltd

**PHONE:** 1800 226 334 - Janssen Medical Information Department

**REASON:** Janssen has received two complaints for Journista 8 mg tablets batch IALS400, due to damage to the blister strips (4 damaged strips in total). This could potentially compromise the blisters integrity, in addition some of the tablets contained within these blisters had visible damage to the coating.

Consumption of a damaged tablet may cause 'dose-dumping' and fluctuation in plasma concentration levels.

This action is being undertaken as a precautionary measure, Janssen have not received any reports of injury as a result of this anomaly.

Further information is available on the TGA and Janssen Australia websites.

**PROPOSED CUSTOMER ACTIONS:**

1. Pharmacists and Customers are requested to visually check for any damage to the blister packs; and
  - If there is damage, please do not use the product and return the pack accordingly; or
  - If there is no damage please carry on using the product as usual.

2. Pharmacists are also requested to contact all customers to whom have been supplied Journista 8mg 14 pack, since the 5th December 2018.

Further information is available on the TGA and Janssen websites:  
[Jurnista \(hydromorphone hydrochloride\) prolonged-release](#) ; and  
<https://www.janssen.com/australia/>

3. Wholesalers have been asked to quarantine any affected stock on hand prior to return to Janssen.

A medicine shortage is not expected as a result of these actions.

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: Retail and Hospital pharmacies and nationally, via 37 wholesalers.

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>