

19 August 2024

Customer Circular

URGENT MEDICINE RECALL

PALEXIA SR 50mg tapentadol

28 tablet blister pack

Lot Number: 136V01 Expiry Date: 07/2026

AUST R: 165332

TGA Ref: RC-2024-RN-00723-1

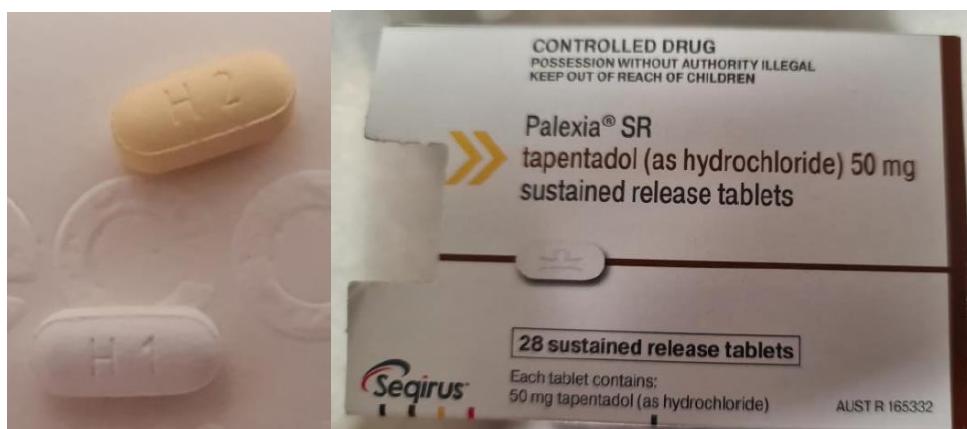
Dear Pharmacist,

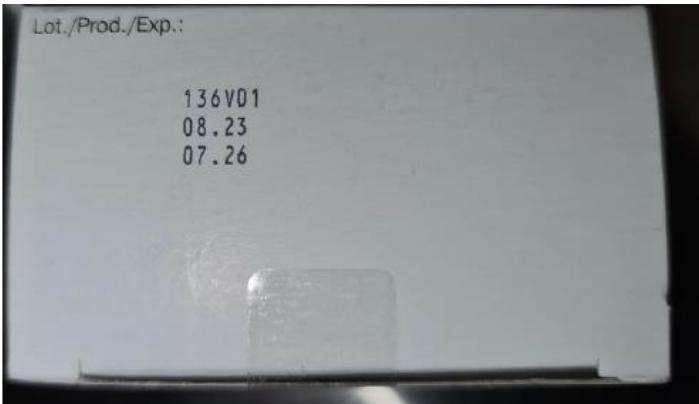
CSL Seqirus, following agreement with the Therapeutic Goods Administration (TGA), is conducting an Urgent Medicine Recall of the above lot of PALEXIA SR 50mg (tapentadol) 28 tablet blister pack.

WHAT IS THE PROBLEM?

- A single blister of PALEXIA SR 50mg Lot 136V01 has been reported to allegedly contain one PALEXIA SR 100mg tablet.
- PALEXIA SR 50mg tablets are white in colour and are stamped with 'H1'.
- PALEXIA SR 50mg tablets are not visible inside the blister so tablets can only be identified upon use.

Below: PALEXIA SR 50mg tablet marked H1 and PALEXIA SR 100mg tablet marked H2, PALEXIA SR 50mg packaging.



	<p>Below: PALEXIA SR packaging showing potentially affected lot</p> 
WHAT IS THE HAZARD/RISK?	<ul style="list-style-type: none">This recall is a precautionary measure to minimise the risk of patients unintentionally ingesting a higher dose of tapentadol than what was prescribed.As with all opioids, the risk of harm (including possible respiratory depression) and adverse effects (e.g. drowsiness, dizziness) increase with higher doses, with elevated risk in specific more vulnerable populations.There is no defect in the quality, safety or efficacy of the tablets themselves.
WHAT SHOULD PHARMACISTS DO UPON RECEIVING THIS LETTER? 	<ul style="list-style-type: none">Inspect your PALEXIA SR 50mg stock immediately and quarantine affected stock of Lot 136V01 on hand to prevent further use.If you have stock on hand of Lot 136V01, destroy it as per the relevant legislation. Capture images of affected stock and a record of destruction.Complete the Customer Response form available here or via the QR Code immediately, even if you do not have any affected stock, so we can reconcile this urgent medicine recall and arrange replacement stock.Ensure relevant staff members are informed of this medicine recall.If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter immediately.Place this letter in a prominent position for at least one month.
HOW WILL THIS BE RESOLVED?	<ul style="list-style-type: none">Other unaffected lots of PALEXIA SR 50mg are currently available for order. Please contact CSL Seqirus Customer Service to arrange.
CONTACT INFORMATION	<p>For questions regarding this letter, please contact:</p> <p>CSL Seqirus Customer Service Phone: 1800 008 275 Email: customer.service.au@seqirus.com</p>

Thank you for your assistance in helping us to manage this medicine recall. CSL Seqirus sincerely regrets any inconvenience caused to your organisation.

Kind Regards,

Dr Jonathan Anderson
Regional Head of Medical Affairs, Asia Pacific
CSL Seqirus

Linda Curran
Head of Quality Assurance Batch Release
CSL Seqirus

Contact number: 1800 008 275 (CSL Seqirus Customer Service)

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