



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 25 March 2020

EL (20)A/18

Our Ref: MDR 151-01/20

Dear Healthcare Professional,

Mylan UK Healthcare Ltd

Zamadol SR 50 mg prolonged-release hard capsules

PL 46302/0149

Batch Number	Expiry Date	Pack Size	First Distributed
8L221D	09/2021	60	30/05/2019
9B225A	01/2022	60	30/09/2019

Active pharmaceutical ingredient: tramadol hydrochloride

Brief description of the problem

Mylan UK Healthcare Ltd has informed us that the GTIN barcode applied on the above batches is incorrect. The GTIN number that should have been allocated for these batches of capsules is 05060035240173, however, 05060035241477 was applied in error which scans the batches as Zamadol Melt Tablet 50mg. All other information on the carton and label, including the EAN barcode is correct for the above batches of Zamadol SR 50 mg prolonged-release hard capsules.

There may be residual risk in cases where wholesalers and pharmacies use automated inventory system to dispense the affected batches within the pharmacy or wholesale facility. Due to concerns with continuity of supply these batches are not being recalled at this time.

Advice for healthcare professional

- The GTIN barcode should not be used for any dispensing activities for the affected batches listed above. Please bring this notice to the attention of all relevant staff within your facility.
- If you have supplied units from this batch to any other pharmacy or clinic, please forward a copy of this Alert to them.

Advice for wholesalers

- The GTIN barcode should not be used for any dispensing activities for the affected batches listed above. Please bring this notice to the attention of all relevant staff within your facility.
- If you have supplied units from this batch to any other pharmacy or clinic, please forward a copy of this Alert to them.



Further Information

For more information or medical information enquiries please contact Mylan UK Healthcare Ltd. Medical Information Department on +44(0) 1707 853000 or via email on Info.uk@mylan.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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