



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 05 December 2022

EL (22)A/50

Our Ref: MDR 206-11/22

Dear Healthcare Professional,

ADVANZ PHARMA T/A Mercury Pharmaceuticals Limited

MacroBID 100mg Prolonged-Release Capsules

PL 12762/0052

SNOMED Code 517311000001102

Batch No	Expiry Date	Pack Size	First Distributed
21001	05 2023	14 capsules	12/08/2022
21002	05 2023	14 capsules	12/08/2022
21003	05 2023	14 capsules	18/08/2022
22001	12 2023	14 capsules	10/08/2022
22002	12 2023	14 capsules	16/09/2022
22003	12 2023	14 capsules	23/09/2022
22006	03 2024	14 capsules	28/09/2022
22007	04 2024	14 capsules	03/10/2022

Active Pharmaceutical Ingredient: Nitrofurantoin

Brief description of the problem:

ADVANZ PHARMA has made the MHRA aware that the above batches of MacroBID 100mg Prolonged-Release Capsules have been packed with the incorrect Patient Information Leaflet (PIL). The PIL does not contain important safety information relating to Possible Side effects and has minor editorial inconsistencies.

Missing safety information from the PIL:

Section 4. Possible Side effects	<ul style="list-style-type: none">• Scarring due to damaged lung tissue may occur• In rare cases, it may cause liver failure which may be fatal• Damage to bone marrow causing deficiency of the red blood cells (anaemia).
----------------------------------	---

Please note, the minor editorial inconsistencies have not been listed as they have no impact on the information contained within the PIL. These will be corrected in all future batches of MacroBID 100mg Prolonged-Release Capsules.



Medicines & Healthcare products Regulatory Agency

Advice for healthcare professionals:

Healthcare professionals should note that there is no risk to product quality and efficacy, therefore the affected batches are not being recalled.

Healthcare professionals are advised to exercise caution when dispensing the above batches. Please provide a copy of the Summary of Product Characteristics (SmPC) when dispensing this medication to patients. This can be downloaded via the following link:
<https://www.medicines.org.uk/emc/product/429/smpc>

ADVANZ PHARMA has confirmed that all future batches will contain the correct PIL. Upon request, ADVANZ PHARMA will post hard copies of the updated PIL and/or SmPC to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information.

Advice for patients:

Patients should be aware that some packs of MacroBID 100mg Prolonged-Release Capsules may contain the incorrect Patient Information Leaflet (PIL). The incorrect PIL does not contain important safety information relating to Possible Side effects.

If you have any questions about your medicine or are concerned about side effects, talk to your healthcare professional. The medicine itself is not affected and any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).

Further Information:

For further information, medical enquiries, stock information or request for printed copy of the associated SmPC, please contact telephone: + 44 (0) 208 5889 131 or via email:
medicalinformation@advanzpharma.com

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

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk