



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 12 September 2022

EL (22)A/38

Our Ref: MDR 025-09/22

Dear Healthcare Professional,

Quadrant Pharmaceuticals Limited

Bezalip Mono 400mg Tablets

PLPI 20774/0036

Batch No	Expiry Date	Pack Size	First Distributed
J3594	09/2025	30	17/11/2021
J3741	09/2025	30	30/11/2021
J3943	09/2025	30	15/12/2021
K0077	01/2026	30	25/01/2022
K0310	01/2026	30	08/02/2022
K0327	12/2025	30	10/02/2022
K0455	09/2025	30	11/02/2022
K0547	12/2025	30	22/02/2022
K0549	09/2025	30	22/02/2022
K0562	01/2026	30	23/02/2022
K2019	01/2027	30	10/06/2022
K1994	01/2027	30	17/06/2022
K2196	01/2027	30	01/07/2022
K2274	10/2026	30	06/07/2022
K2742	01/2027	30	26/07/2022
K2943	01/2027	30	18/08/2022
K3158	01/2027	30	24/08/2022
K3134	01/2027	30	30/08/2022

Active Pharmaceutical Ingredient: bezafibrate

Brief description of the problem:

Quadrant Pharmaceuticals Limited have informed the MHRA of an error with the Patient Information Leaflets (PILs) that have been packaged in the above parallel imported batches. The PIL included in the batches above is an older version of the PIL, which does not include the most up to date safety information.

The information missing from the PILs are as below:

Section 4. Possible side effects

Contact your doctor immediately if you notice signs of:

- severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson Syndrome)
- severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (Toxic epidermal necrolysis).



Medicines & Healthcare products Regulatory Agency

Advice for healthcare professionals:

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to discuss the missing information with patients and provide a copy of the updated PIL, where appropriate. MHRA PIL Link: [Bezalip Mono 400mg Tablets PLPI 20774/0036](#)

Quadrant Pharmaceuticals Limited have confirmed that no further units of any of the above batches will be released, therefore this notification only applies to packs that are already at pharmacy or wholesaler level, or in the possession of patients.

Quadrant Pharmaceuticals Limited have also confirmed that all future batches will contain the updated PIL and that upon request they will send hard copies by post of the updated PIL to wholesalers and pharmacies, so that any remaining stock in the dispensary can be supplemented with the updated PIL information.

Advice for patients:

Patients should be aware that the Patient Information Leaflet (PIL) in the above batches does not contain the most up to date safety information on skin side effects.

If you experience any of the side effects listed below, you should contact your doctor immediately:

- severe form of skin rash with flushing, fever, blisters or ulcers
- severe rash involving reddening, peeling and swelling of the skin that resembles severe burns

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 also be reported via the [MHRA Yellow Card scheme](#).

Further Information:

For more information, medical or supply enquiries, please contact radoslaw.bandomir@maxearn.co.uk or natalie.harrison@hallohealthcaregroup.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