Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 14 December 2020 EL (20)A/58 Our Ref: MDR 077-11/20

Dear Healthcare Professional,

Generics [UK] Limited t/a Mylan

Perindopril Erbumine 2 mg Tablets PL 04569/1348

Batch Number	Expiry Date	Pack Size	First Distributed
3109619	11/2021	30	06 May 2020
3116084	04/2022	30	24 August 2020

Perindopril Erbumine 4 mg Tablets PL 04569/1349

Batch Number	Expiry Date	Pack Size	First Distributed
3112399	01/2022	30	28 July 2020
8104332	01/2022	30	16 August 2020

Perindopril Erbumine 8 mg Tablets PL 04569/1350

Batch Number	Expiry Date	Pack Size	First Distributed
8104319	01/2022	30	28 July 2020

Active pharmaceutical ingredient: Perindopril Erbumine

Brief description of the problem
Generics [UK] Limited t/a Mylan have informed us that the Patient Information Leaflet (PIL) within the packs for the products listed above is missing relevant important safety information. The corrected sections of the PIL include the addition of the information listed below:

Section in PIL	Missing information
Section 2 Do not take Perindopril Erbumine:	• if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Perindopril Erbumine may not be suitable for you. • if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).

Section 2 Warnings and precautions. Talk to your doctor or pharmacist before taking Perindopril Erbumine if you:	• have abnormally increased levels of a hormone called aldosterone in your blood (primary aldosteronism)
Section 4 Other possible side effects:	Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible.
Section 4 Reporting of side effects	or search for MHRA Yellow Card in the Google Play or Apple App Store.

It is important that any patients who have been prescribed the products are provided with information on warnings and precautions whilst taking Perindopril Erbumine. Additionally, patients who notice the symptoms/side effects should seek immediate medical advice.

Advice for healthcare professionals
When dispensing the above products and batches, please check the Marketing Authorisation Holder and if any of the batches of the product above are being dispensed, ensure that patients are aware of any missing information. Generics [UK] Limited t/a Mylan have stopped distribution of all affected batches, therefore stock received from January 2021 from wholesalers will be compliant with the new leaflet.

Further Information
For more information or medical information queries, please contact: Generics [UK] Limited t/a Mylan Medical Information Direct Line +44 (0)1707 853 000 select option 1, Customer Care direct line +44 (0)1707 853 000 select option 2 or via Medical Information e-mail info@mylan.co.uk.

Recipients of this Drug Alert 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