

Drug Alert

Caution-in-Use

Date: 06/03/2023

Our Ref: MDR 029-02-2023-CA

Dear Healthcare Professional,

Atnahs Pharma Netherlands B.V.

Zestoretic 20mg/12.5mg Tablets

MA1310/00301

Batch No	Expiry Date	Pack Size	First Distributed
SA575	Jan 2024	28 units	27 May 2022

Active Pharmaceutical Ingredient: fixed dose combination product containing Lisinopril (ACE inhibitor) and Hydrochlorothiazide (Diuretic)

Brief description of the issue

Atnahs Pharma Netherlands B.V has informed the Malta Medicines Authority that the Patient Information Leaflet (PIL) packaged in the above batch of Zestoretic 20mg/12.5mg Tablets contains outdated safety information.

Details of the discrepancies are listed below:

The Safety update relates to the CMDh & Pharmacovigilance Risk Assessment Committee (PRAC) recommended update to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) to include specific text to alert prescribers and patients of a new information that relates to a side effect classified as having a very rare frequency (less than 1 in 10,000).

The PIL text changes required to have been implemented are as follows:

Section 2

'If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Zestoretic, seek medical attention immediately'

Section 4 Very Rare side effect

'Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)'

The Summary of Product Characteristics (SmPC) and PIL are up to date:

<https://medicinesauthority.gov.mt/medicine-details?id=85550>

These are the correct SmPC's.

Advice for healthcare professionals

There is no risk to product quality as a result of this issue. Healthcare professionals are advised to exercise caution when dispensing the above batches of the product. Where possible, please provide an updated copy of the PIL to the patient and remind the patient to **read the leaflet in its entirety before using the medicine**. This is available via the link below:

<https://medicinesauthority.gov.mt/medicine-details?id=85550>

Advice for patients

Patients should be aware that the PIL in the above batch SA575 does not contain the most up-to-date safety information. Include details of missing safety information

Section 2

'If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Zestoretic, seek medical attention immediately'

Section 4

'Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)'

Any suspected adverse reactions should be reported via the Malta Medicines Authority

<https://medicinesauthority.gov.mt/form-details?surID=39&cat=3>

Further Information

For more information, medical information queries, replacement PIL enquiries and stock queries, please contact: info@pharmanovia.com

Yours faithfully,

Christopher Attard

Senior Medicines Inspector