



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 27 February 2023

EL (23)A/05

Our Ref: MDR 143-02/23

Dear Healthcare Professional,

### Atnahs Pharma UK

Zestoretic 20mg/12.5mg Tablets

PL 43252/0035

SNOMED Code 17403011000001101

Batch No	Expiry Date	Pack Size	First Distributed
SB012	Apr 2024	28 units	7 Sep 2022

Active Pharmaceutical Ingredient: Lisinopril and Hydrochlorothiazide

#### Brief description of the issue

Atnahs Pharma UK has informed the MHRA that the Patient Information Leaflet (PIL) packaged in the above batch of Zestoretic 20mg/12.5mg Tablets contains outdated safety information. Healthcare professionals should note that the critical missing information is contained within Section 4 of the incorrect PIL, however it is not in line with the recommended update to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL). It omits specific text to alert prescribers and patients to new information that relates to a side effect classified as having a very rare frequency (less than 1 in 10,000). Details of the discrepancies are listed below:

#### 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).'*

The SmPC and PIL are up to date:

- [Zestoretic 20mg/12.5mg Tablets - PL 43252/0035 – SmPC](#)
- [Zestoretic 20mg/12.5mg Tablets - PL 43252/0035 – PIL](#)

Full text link for SmPC:

<https://mhraproducts4853.blob.core.windows.net/docs/a5b5e2b8d78e4b987c88906b899fa759f0394bb5>

Full text link for PIL:

<https://mhraproducts4853.blob.core.windows.net/docs/aa4ecef3f6ff1689a1d571ca3c53009157d05eb4>



### 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 following link: [Zestoretic 20mg/12.5mg Tablets - PL 43252/0035 – PIL](#)

Where available, Atnahs Pharma UK will be providing the updated PIL with all future deliveries of Zestoretic 20mg/12.5mg Tablets. Upon request, Atnahs Pharma UK will post hard copies of the updated PIL 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 the PIL in the Zestoretic 20mg/12.5mg Tablets batch SB012 does not contain the most up-to-date safety information. The missing information is listed below. Patients should be aware that Section 4 of the incorrect PIL contains information on serious side effects, but does not elaborate on these side effects. Details of the missing information is included below:

#### 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)'.*

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should be reported via the MHRA [Yellow Card scheme](#).

### Further Information

For more information, medical information queries, replacement PIL enquiries and stock control queries, please contact: [info@pharmanovia.com](mailto:info@pharmanovia.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](mailto:DMRC@mhra.gov.uk)**