

SB TITCK 13.11.2023 HIDROKLOROTİYAZİD İÇEREN İLAÇLAR ACIL GÜVENLİLİK KISITLAMASI_EN

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-1284008 13.11.2023 Subject:
Hydrochlorothiazide-containing products – Urgent safety restriction

FILE

The Agency has given consideration to a decision taken by the European Medicines Agency regarding hydrochlorothiazide-containing products (PSUSA/00001662/202101- acute respiratory toxicity). Accordingly, the wording provided in the attachment must be incorporated in the local summary of product characteristics (SmPC) and package leaflet (PL) of all medicines containing hydrochlorothiazide. Copies of local SmPC/PL of reference products, incorporating the aforesaid changes, must be submitted to the Pharmacological Assessment Unit within 15 days from the date of announcement. For other products containing hydrochlorothiazide, a submission must be made to the Pharmacological Assessment Unit within 15 days from the posting date of local SmPC/PL of reference products on the Agency's official website. For products containing the aforesaid substance which has not a reference product or which has not an actively marketed reference, the submission to the Pharmacological Assessment Unit must be made within 15 days of the announcement, without waiting for posting of reference product's local SmPC/PL on the Agency's official website. For your information and appropriate action.

Dr. Asım Hocaoglu Agency President

Attachment: Wording to incorporate in the local SmPC/PL (1 page)

Distribution: For appropriate action: Turkish Pharmaceutical Manufacturers' Association
Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers'
Association of Türkiye Health Products Association

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LOCAL SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special Precautions and Warnings for Use

Acute Respiratory Toxicity Very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported after taking hydrochlorothiazide. Pulmonary edema typically develops within minutes to hours after hydrochlorothiazide intake. At the onset, symptoms include dyspnea, fever, pulmonary deterioration and hypotension. If diagnosis of ARDS is suspected, treatment with ...(product name)... should be stopped and appropriate treatment given. Hydrochlorothiazide should not be administered to patients who previously experienced ARDS following hydrochlorothiazide intake.

4.8 Undesirable Effects

Under the subheading for Respiratory, thoracic and mediastinal disorders: Very rare: Acute respiratory distress syndrome (ARDS) (see Section 4.4)

LOCAL PACKAGE LEAFLET

2. What you need to know before you use

EXERCISE CAUTION when using: • if you experienced breathing or lung problems (including inflammation or fluid buildup in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking, seek medical attention immediately.

4. Possible side effects

Very rare: • Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

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