

ANJİYOTENSİN II RESEPTÖR BLOKERLERİ- ACIL GÜVENLİLİK KISITLAMASI_EN

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-5607709 14.03.2025 Subject: Angiotensin II Receptor Blockers - Urgent Safety Restriction

FILE

The European Medicines Agency's (EMA) warning titled "Signal assessment report on intestinal angioedema with angiotensin II receptor blockers" regarding drugs containing angiotensin II receptor blockers has been evaluated by our Agency. The attached statements should be added to the Summary Product Characteristics (KÜB) and Patient Information Leaflet (KT) of these drugs. Accordingly, • For the reference products falling within the scope of the Decision, an application should be submitted by the marketing authorization holder to the Pharmacological Evaluation Unit of the Pharmaceuticals Licensing together with KÜB/KT of the relevant reference products reflecting the changes in question, • For other products falling within the scope of the decision, an application should be submitted by the marketing authorization holder to the Pharmacological Evaluation Unit of the Pharmaceuticals Licensing Department within 15 days following the publication of the updated KÜB/KT of the reference product on the official website of the Agency, • For products falling within the scope of the Decision but do not have a reference or whose reference is not active in the market, an application for change of KÜB/KT should be submitted by the marketing authorization holder to the Pharmacological Evaluation Unit of the Pharmaceuticals Licensing Department within 15 days from the date of the announcement, without waiting for the KÜB/KT text of any reference drug to be published on the official website of the Agency, For your information and necessary actions.

Prof. Dr. Ahmet AYAR Agency President

Attached: KÜB/KT Text (2 pages)

To be distributed to: Pharmaceutical Industry Employers' Association Association of Research-Based Pharmaceutical Companies Turkish Pharmaceutical Industry Association Health Products Association Drug, Pharmacy, Health Science and Technologies Foundation (İVEK) Developmental Pharmaceutical Companies Association

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SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special warnings and precautions for use

Olmesartan, irbesartan, valsartan, losartan and candesartan (single component or fixed-dose combination component):

Intestinal angioedema: Intestinal angioedema has been reported in patients treated with angiotensin II receptor blockers [including <drug name>] (see section 4.8). These patients complained of abdominal pain, nausea, vomiting and diarrhea. Their symptoms improved after discontinuation of the angiotensin II receptor blocker. If intestinal angioedema is diagnosed, treatment with <drug name> should be discontinued and appropriate monitoring initiated until complete resolution of symptoms.

Azilsartan, eprosartan and telmisartan (single component or fixed-dose combination component):

Intestinal angioedema: Intestinal angioedema has been reported in patients treated with angiotensin II receptor blockers (see section 4.8). These patients complained of abdominal pain, nausea, vomiting and diarrhea. Their symptoms improved after discontinuation of the angiotensin II receptor blocker. If intestinal angioedema is diagnosed, treatment with <drug name> should be discontinued and appropriate monitoring initiated until complete resolution of symptoms.

4.8 Undesirable effects

For olmesartan, irbesartan, valsartan, losartan and candesartan: addition to the adverse reaction table for the corresponding ARB. For losartan, olmesartan and irbesartan, the frequency should be “rare”. For valsartan and candesartan, the frequency should be “very rare”:

Gastrointestinal disorders

Intestinal angioedema

Azilsartan, eprosartan and telmisartan (single component or fixed-dose combined component):

Description of selected adverse reactions: Cases of intestinal angioedema have been reported after the use of angiotensin II receptor blockers (see section 4.4).

PATIENT INFORMATION LEAFLET

For all ARBs (olmesartan, azilsartan, candesartan, eprosartan, irbesartan, valsartan, losartan and telmisartan):

2. What you need to know before you use <drug name>

Warnings and precautions Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhea after taking <drug name>. Your doctor will decide on further treatment. Do not stop taking <drug name> on your own.

4. Possible side effects

For olmesartan, irbesartan, valsartan, losartan and candesartan: addition to the adverse reaction table for the corresponding ARB. For losartan, olmesartan and irbesartan, the frequency should be “rare”. For valsartan and candesartan, the frequency should be “very rare”:

Intestinal angioedema: swelling of the bowels with symptoms such as abdominal pain, nausea, vomiting and diarrhea

For azilsartan, eprosartan and telmisartan:

Frequency 'unknown': Intestinal angioedema: Swelling of the bowels with symptoms such as abdominal pain, nausea, vomiting and diarrhea has been reported after use of similar products.