

SB TITCK 24.03.2025 MONTELUKAST İÇEREN İLAÇLAR ACIL GÜVENLİLİK KISITLAMASI_İNG

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-5616098 22.03.2025 Subject: Montelukast Containing Medicines - Urgent Safety Restriction

FILE

Based on the warnings of the European Medicines Agency (EMA), Coordination group for Mutual recognition and Decentralized procedures (CMDh) concerning all medicinal products containing montelukast, regarding the request for stronger emphasis on the statements for neuropsychiatric events in the product information of medicinal products containing montelukast, a decision was taken to add the statements specified in the attached document to the Summary of Product Characteristics (KÜB) and Patient Information Leaflet (KT) of these medicinal products. The warnings regarding neuropsychiatric events have been evaluated by our Agency and it has been decided to add the attached statements to the Summary of Product Characteristics (KÜB) and Patient Information Leaflet (KT) of medicines containing montelukast licensed in Turkey. Accordingly: 1. For the reference products covered by the Decision, the marketing authorization holders should apply to the Pharmacological Evaluation Unit of the Pharmaceuticals Registration Department within 15 days from the date of the announcement, together with the KÜB's/KT's of the relevant reference products reflecting the changes in question, 2. Within 15 days following the publication of the updated KÜB's/KT's of the reference product on the official website of the Agency, an application should be made by the marketing authorization holders to the Pharmacological Evaluation Unit of the Pharmaceutical Registration Department for other products covered by the decision, 3. For products that fall within the scope of the Decision but do not have a reference or whose reference is not active in the market, the marketing authorization holders should apply to the Pharmacological Evaluation Unit of the Pharmaceuticals Registration 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 action.

Prof. Dr. Ahmet AYAR Agency President

Attached: KÜB/KT Text (1 page)

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 Association of Developmental Pharmaceutical Companies

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Summary of Product Characteristics (KÜB)

4.4 Special warnings and precautions for use

Statements about neuropsychiatric events should be changed to be in boldface and boxed:

Neuropsychiatric events including behavioral changes, depression and suicidal tendencies have been reported in all age groups receiving montelukast (see section 4.8). Symptoms can be serious and may persist if treatment is not discontinued. Therefore, treatment with montelukast should be discontinued if neuropsychiatric symptoms occur during treatment. Advise patients and/or caregivers to be alert for neuropsychiatric events and tell patients to inform their doctor if these changes in behavior occur.

Patient Information Leaflet (KT)

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

Statements about neuropsychiatric events should be changed to be in boldface and boxed:

Several neuropsychiatric events (e.g. changes in behavior and mood, depression and suicidal tendency) have been reported in patients of all ages treated with Montelukast (see section 4). If you develop such symptoms while taking Montelukast, you should contact your doctor.