

26.06.2024 MIDAZOLAM İÇEREN İLAÇLAR – ACIL GÜVENLİLİK KISITLAMASI_EN

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-1518849 26.06.2024 Subject: Midazolam-containing drugs
– Urgent Safety Restriction

DOSSIER

Reference is made to the announcement that the warnings for “Kounis Syndrome,” which the European Medicines Agency (EMA), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Medicinal Products for Human Use (CHMP) had issued for products containing midazolam (for all pharmaceutical forms and therapeutic indications, excluding oromucosal solution indicated for the treatment of prolonged, acute, convulsive seizures), would need to be incorporated in product information of midazolam-containing drugs in Europe. The Agency has given consideration to the warnings and decided that the wording provided in the attachment must be incorporated in the local summary of product characteristics (KÜB) and local package leaflet (KÜB) of the aforesaid products. KÜB for reference products reflecting the required changes should be submitted to the Pharmacological Assessment Unit within 15 days of the announcement. For other products containing midazolam, a submission to the Pharmacological Assessment Unit should be made within 15 days after the KÜBs for reference products have been posted on the Agency’s official website. For products which contain this active substance but which have not a reference or an actively-marketed reference, a submission should be made to the Pharmacological Assessment Unit within 15 days of the announcement, without waiting for posting of KÜB for a reference product on the Agency’s official website. For your information and appropriate action.

Dr. Asım Hıcaoğlu Agency President

Distribution: Turkish Pharmaceutical Manufacturers’ Association Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers’ Association of Türkiye Health Products Association

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Amendments to be included in the relevant sections of the Product Information (new text underlined and in bold, deleted text strike through).

Local Summary of Product Characteristics (KÜB)

4.8 Undesirable effects The following adverse reaction should be added under the System Organ Class “Cardiac disease” with a frequency of “Not known.”

Kounis syndrome*

*particularly before parenteral administration.

Local Package Leaflet (KT)

4. Possible side effects

[...]

Oral formulations:

Immune system disorders; Susceptible persons may experience hypersensitivity reactions and angioedema.

Chest pain has been observed, as a sign of a serious allergic reaction called the Kounis syndrome.

All other pharmaceutical forms (excluding oral formulations):

[...]

If you experience any of the following, stop taking <Product name> and IMMEDIATELY see your doctor or seek urgent medical attention at the nearest hospital:

Anaphylactic shock (a life-threatening allergic reaction). Signs may include a sudden rash, itching or lumpy rash (hives) and swelling of the face, lips, tongue or other parts of the body. You may also have shortness of breath, wheezing or trouble breathing, a pale skin, a weak and rapid pulse or loss of consciousness. Additionally, you may experience chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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