

**SB TITCK 25.92.2025 DİKLOFENAK İÇEREN İNTRAMÜSKÜLER İLAÇLAR – ACIL GÜVENLİLİK
KISITLAMASI İNG**

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-5592866 25.02.2025 Subject: Diclofenac-Containing
Intramuscular Drugs - Urgent Safety Restriction

FILE

The complaints and notifications received by our Agency regarding intramuscular medicinal products containing diclofenac sodium have been evaluated and it has been decided to add the attached statements to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of these medicinal products. Accordingly: 1. For the reference products covered by the Decision, the marketing authorization holder should apply to the Pharmacological Evaluation Unit of the Pharmaceuticals Registration Department within 15 days from the date of the announcement, together with the SmPCs/PILs of the relevant reference products reflecting the changes in question, 2. Within 15 days following the publication of the updated SmPCs/PILs of the reference product on the official website of the Agency, an application should be made by the marketing authorization holder 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 holder 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 SmPC/PIL 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: SmPC/PIL Text (1 page)

Distribution: 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

SUMMARY OF PRODUCT CHARACTERISTICS

4.4 Special Warnings and Precautions for Use Instructions for intramuscular injection should be strictly followed to avoid injection site adverse reactions that may result in muscle weakness, muscle paralysis, hypoesthesia, embolia cutis medicamentosa (Nicolau syndrome) and injection site necrosis. Injection site reactions: Injection site reactions have been reported after intramuscular administration of diclofenac, including injection site necrosis and embolia kutis medicamentosa, also known as Nicolau syndrome (especially after inadvertent subcutaneous administration). During intramuscular administration of diclofenac, the appropriate needle should be selected, and the appropriate injection technique should be followed.

PATIENT INFORMATION LEAFLET

If any of the following happen, stop taking <drug name> and tell your doctor IMMEDIATELY or contact the emergency department of the nearest hospital: Injection site reactions including pain, redness, swelling, hard lump, sores and bruising at the injection site. This can progress to blackening and death of the skin and underlying tissues surrounding the injection site, healing with scarring, also known as Nicolau syndrome.

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