

SB TITCK 09.04.2024 NON-STEROIDAL ANTIINFLAMATUAR İLAÇLAR HK.- GÖRÜŞ KATKI_EN

Turkish Ministry of Health Turkish Medicines and Medical Devices Agency
Number: E-62820468-000-1444545 09.04.2024 Subject: Non-steroidal anti-inflammatory drugs

DOSSIER

Reference: Announcement dated 23.10.2012 to unions/associations on non-steroidal anti-inflammatory drugs

In view of the data available, our Agency's Clinical Assessment Unit has reconsidered the previous announcement to unions/associations on "non-steroidal anti-inflammatory drugs." Specifically: • Non-steroidal anti-inflammatory drugs (NSAIDs) have short- or long-acting, COX-2-selective or non-selective variants. Moreover, NSAIDs vary in their anti-inflammatory, analgesic and antipyretic properties. NSAID-containing drugs are not identical in their efficacy and safety, and therefore it has been less than optimal to standardize their therapeutic indications. • Clinical data is not available for all NSAID-containing drugs for all of the therapeutic indications specified in the aforesaid announcement to unions and associations. • Also, NSAID-containing drugs have differences in their therapeutic indications as specified in their respective SmPCs. Based on the reasons described above, the aforesaid announcement to unions and associations is hereby withdrawn to enable assessment based on the clinical data available for each active substance and pharmaceutical form, rather than lumping all active substances classified as an NSAID in a single announcement to unions and associations. Please forward any opinions, suggestions or contributions concerning the decision above to the Clinical Assessment Unit within 10 (ten) days after the issuing date of this announcement to unions and associations, and in the meantime abstain from submitting any applications to the Pharmacological Assessment Unit or the Registration Unit concerning "Non-steroidal anti-inflammatory drug-containing products." For your information and appropriate action.

For the Agency President F. Handan Öztunca, M.Sc., Pharm. Department Head

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers' Association of Türkiye Turkish Pharmaceutical Manufacturers' Association Association of Progressive Pharmaceutical Companies Health Products Association Pharmaceuticals, Pharmacy, Health Sciences and Technologies Foundation

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Turkish Ministry of Health Medicines and Medical Devices Agency of Turkey Office of the Vice-President for Medicines and Biological and Medicinal Products

Number: B.10.1.TİT.0.02.0.01.0.07.03 ANKARA Subject: Non-steroidal anti-inflammatory drugs

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According to a decision adopted by the "Advisory Committee to the Agency for Registration of Human Medicinal Products" concerning NSAIDs (non-steroidal anti-inflammatory drugs), the indications section for these products will be revised as follows: "Indicated for the treatment of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis, and for the treatment of acute gouty arthritis, acute musculoskeletal pain, postoperative pain, and dysmenorrhea." Please advise the members of your Union/Association to take account of the above information for their existing and future SmPC/PL submissions to our Agency.

Dr. Saim Kerman Agency President Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers' Association of Turkey Turkish Pharmaceutical Manufacturers' Association Association of Progressive Pharmaceutical Companies Health Products Association

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