

**05.12.2019 TARİHLİ VE E.206228 TARİHLİ DERMATOLOJİ ENDİKASYONUNDA KULLANILAN
METOTREKSAT İÇEREN İLAÇLAR HK._ENG**

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency

NORMAL
05.12.2019

DOSSIER

The relevant indications of the doses not surpassing 30 mg of products in tablet form and injectable form containing “methotrexate” used in dermatological indications should be amended as “It is indicated for moderate and severe treatment of psoriasis not responding to conventional therapies”.

I hereby submit for your information and kindly request for the conduct of relevant action for the submission of the SPC/PL applications of the products in which abovementioned changes are made to the Pharmacological Evaluation Unit until 13.01.2020 for review.

Eray KAPLAN Deputy President of the Agency

Distribution: Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Turkish Pharmaceutical Industry Association Association of Innovator Pharmaceutical Companies Self-Care Products Association

Number : 62820468-000-E.206228 Subject : Products containing methotrexate used in dermatological indications