

RESTRICTED

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

NORMAL
27.03.2019

DOSSIER

Ref: Our Association announcement on “Medicines containing vitamin D”, dated 18.03.2019, with No. E.46137. It is necessary to remove the term “oral” from the product name and Summary of Product Characteristics and Package Leaflet of the products containing 300.000 I.U. / mL vitamin D and including the term “oral” in the product name and to submit an application in line with our Association announcement.

I hereby submit for your information and kindly request that the SPC/PL applications relating to the products in which abovementioned changes are made are sent to the Clinical Evaluation Unit until 19.04.2019 for review.

Dr. Hakkı GÜRSÖZ 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

No. : 62820468-000-E.51756 Subject : Medicines containing vitamin D