

DOCUMENT

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

Number : E-24931227-000-374639 Subject : Oral Preparations Containing Levothyroxine
NORMAL 18.03.2021

DOSSIER

Ref: Announcement to associations, 22.09.2017, with No. E.188954.

The referred announcement on the “medicines containing levothyroxine” has been revoked and the applicable decision for associations is as follows.

Due to the fact that the co-administration of the oral preparations containing levothyroxine with the medicines containing the active substances “Aluminum, Magnesium, Simethicone, Calcium Carbonate, Kayexalate, Iron, Orlistat and Sucralfate” disrupts absorption, it is necessary to add the statements reading “Due to the disruption of absorption in the co-administration of the medicines containing levothyroxine with, these two medicines should be taken at an interval of minimum 2 hours” to the section “4.5 Interactions with other medicinal products and other modes of interaction” in the text of the SPC and the section “Co-administration with other medicines” in the PIL.

The SPC/PIL applications of products in which abovementioned changes are made should be submitted to the Pharmacological Evaluation Unit within 1 month as of the publication date of this association decision for review, the applications for products with ongoing registration process should be submitted to the Registration Unit, and this announcement should be considered for products for which registration application will be made. I hereby submit for your information and kindly request that the referred applications are not submitted to the Clinical Evaluation Unit.

Assoc. Prof. Dr. Tolga TOLUNAY 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 Turkish Foundation on Pharmaceuticals, Pharmacy, Health Sciences and Technologies

REVOKED

RESTRICTED

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

Number : 77893119-501.04-E.188954 Subject : Medicines containing levothyroxine NORMAL
22.09.2017

DOSSIER

Ref: Announcement to associations, dated 31.05.2017, with No. E.117617

Due to the fact that the co-administration of the medicines containing levothyroxine with the medicines containing the active substances “Aluminum, Magnesium, Simethicone, Calcium Carbonate, Kayexalate, Iron, Orlistat and Sucralfate” disrupts absorption, it is necessary to add the statements reading “Due to the disruption of absorption in the co- administration of the medicines containing levothyroxine with, these two medicines should be taken at an interval of minimum 2 hours” to the section “4.5 Interactions with other medicinal products and other modes of interaction” in the text of the SPC and the section “Co- administration with other medicines” in the PIL.

The referred document has been re-evaluated in line with the objection applications of companies and the current data and is no longer valid; I hereby would like to inform you and kindly request that application is made to the “Pharmacological Evaluation Unit” along with the SPC/PIL

samples of the products in which the referred amendments are reflected.

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