

RESTRICTED

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

Number : 62820468-000-E.14148 Subject : Medicines containing the active substance
“Nateglinide” NORMAL

24.01.2019 DOSSIER

The medicines with the active substance “Nateglinide” have been evaluated by the “Clinical Evaluation Commission of Medicinal Products for Human Use” and the relevant sections of the Summary of Product Characteristics (SPCs) and Package Leaflet (PL) of the referred products should be updated in a manner so that they contain and are in line with the following information: Therapeutic indications: • It is indicated for the combination treatment with metformin in patients who cannot be regulated with the maximum tolerated dose of metformin alone in type 2 diabetic patients. Posology and mode of administration (the titles monotherapy and combination treatment should be removed): • Recommended starting dose especially in patients with values close to the targeted HbA1c values is 60 mg to be taken 1-30 minutes prior to main meals three times a day. In case sufficient blood sugar control cannot be achieved with this dose, the dose may be increased to 120 mg three times a day. • Maximum dose of nateglinide is 180 mg to be taken prior to main meals three times a day.

I hereby submit for your information and kindly request that the SPC/PL applications of the products in which abovementioned changes are made are sent to the Pharmacological Evaluation Unit until 18.02.2019 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