

18.08.2019 TARİHLİ VE E.127276 GLP-1 ANALOGLARI-ACIL GÜVENLİLİK KISITLAMASI_, ENG

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

Number: 54398317-510.01.04-E.127276 Subject : GLP-1 analogues – Emergency Safety Restriction NORMAL

18.08.2019

DOSSIER

The following statements need to be added to the SPCs and PLs of the medicines included into the scope of GLP-1 analogues as a result of the evaluation carried out by our Agency regarding the referred medicines.

Summary of Product Characteristics 4.3 Contraindications • It is contraindicated for patients who have medullar thyroid carcinoma themselves or in their family history or for patients with multiple endocrine neoplasia syndrome type 2.

Package Leaflet 2. Take care before using <name of medicine> • Do not use <name of medicine> if you have or a family member has medullar thyroid carcinoma which is a type of thyroid cancer or if you have multiple endocrine neoplasia syndrome type 2 which is an endocrine system disease.

The SPC/PL applications of the reference products in which the referred changes are made should be sent to the Pharmacological Evaluation Unit within 15 days as of the date of announcement for review. Application should be made to the Pharmacological Evaluation Unit for the other medicines containing GLP-1 analogues within 15 days following the publication of the SPC/PL texts of the reference product on our official website. However, for medicines with no reference among the medicines containing the referred active substances or for medicines with no active reference on the market, application should be made to the Pharmacological Evaluation Unit within 15 days as of the date of announcement without having to wait for the publication of the SPC/PL text of any reference medicine on our official website.

I hereby submit for your information for the conduct of relevant information.

Dr. Pharm. Harun KIZILAY Acting President of the Agency

Distribution: For the conduct of relevant action: Turkish Pharmaceutical Industry Association Association of Research-Based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Turkey Association of Innovator Pharmaceutical Companies Self-Care Products Association