

31.05.2019 TARİHLİ TOPIKAL KORTIKOSTEROİD İÇEREN ÜRÜNLER HK.-GÖRÜŞ-KATKI_, ENG

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

NORMAL

31.05.2019

DOSSIER

Topical corticosteroid preparations have been evaluated by the “Clinical Evaluation Commission of Medicinal Products for Human Use”. According to the referred decision; - The decision on associations, dated 07.03.2018, with No. E.44659, on the products containing “Clobetasol propionate” and the decision on associations, dated 30.10.2018, with No. E.188485, on the products containing the active substance “Betamethasone dipropionate”. - It is necessary to add the following statement on the products containing topical corticosteroid included into the following table and regarded as ultra-highly and highly potent, reading “Unless it is necessary, its use is not recommended in the pediatric age group”, to the section on posology of the Summary of Product Characteristics and to include this information also to the relevant section of the Package Leaflet.

Betamethasone Dipropionate Desoximethasone Clobetasol Propionate Diflorasone Diacetate Diflucortolone Valerate Halcinonide Fluocinonide Halobetasol Propionate Flurandrenolide Betamethasone Valerate Amcinonide Fluoticasone Propionate

Regarding the other products containing topical corticosteroid, it is necessary to add the statement reading, “Unless it is necessary, its use is not recommended in infants and small children.” to the section on posology of the Summary of Product Characteristics and to include this information also to the relevant section of the Package Leaflet.

I hereby submit for your information and kindly request that any views, proposals and remarks regarding the decision adopted are submitted to the Clinical Evaluation Unit until 12.07.2019 and that no application is made to the Pharmacological Evaluation Unit regarding products containing topical corticosteroid during the referred process. Dr. Pharm. Nihan Burul BOZKURT on behalf of the President of the Agency Deputy Head of Department

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

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