

ASIKLOVIR ETKİN MADDESİNİ İÇEREN UYGULAMA ŞEKLİ TOPIKAL OLMAYAN ÜRÜNLER HK_ENG

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

12.10.2021

Number : E-24931227-000-563515 Subject : Products Containing the Active Substance
“Acyclovir” with a Non-Topical Mode of Administration

DOSSIER

Products containing the active substance “Acyclovir” with a non-topical mode of administration have been evaluated by the Clinical Evaluation Unit. It is necessary to perform the following changes in the SPC and PL of non-topical products containing the referred active substance and non-topical mode of administration:

The statement reading “It is used in the primary treatment of CMV infections” and “It is used in the prophylaxis of CMV infections in patients who underwent bone marrow transplantation” should be removed.

The warning reading “It is necessary to make dose adjustment and watch out for dehydration in case of renal dysfunction in patients taking acyclovir” should be added.

It is necessary to submit the SPC/PL applications of the products in which abovementioned changes are made to the Pharmacological Evaluation Unit within 1 month as of the publication date of this association decision, to submit the applications for the products with ongoing registration process to the Registration Unit, and to take into account this announcement for products for which registration will be submitted. I hereby submit for your information and kindly request for the conduct of relevant action so that the referred applications are not submitted to the Clinical Evaluation Unit.

Assoc. Prof. Dr. Tolga KARAKAN President of the Agency

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