



## Direct Healthcare Professional Communication

May 2023

### **An Approved Safety Label Change: Risk Of Cushing's Syndrome And Adrenal Suppression With The Use Of Econopred Plus (Prednisolone Acetate) Eye Drops.**

Dear Healthcare Professional,

Novartis, in agreement with The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

#### ***Summary:***

- The implementation of this approved safety information in the leaflet of Econopred Plus has begun; until this is operational and to prevent interruption of supplies, Econopred Plus will continue being supplied with the current leaflet which does not reflect this new safety information.
- We intend to begin the supply of Econopred Plus with the updated safety information in the leaflet at the earliest and until then, can you please take note of the newly added Adverse Drug Reaction (ADR) in the PI.
- This DHPC letter serves to keep you informed of the new ADR (Cushing's syndrome and adrenal suppression) for Econopred Plus for those patients using ophthalmic prednisolone frequently and with a commitment to update the leaflet by May 2023.

#### ***Further information on the safety concern and the recommendations:***

Not applicable

#### ***Further information***

Current approved Indication and usage in Egypt: Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the

globe, such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivites, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.





### Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Hotline: 15301

