

30.08.2020

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא

Advagraf 0.5 mg capsules prolonged release.
Advagraf 1 mg capsules prolonged release.
Advagraf 3 mg capsules prolonged release.
Advagraf 5 mg capsules prolonged release.

חומר פעיל :

Advagraf 0.5 mg: Each capsule contains 0.5 mg tacrolimus (as monohydrate).
Advagraf 1 mg: Each capsule contains 1 mg tacrolimus (as monohydrate).
Advagraf 3 mg: Each capsule contains 3 mg tacrolimus (as monohydrate).
Advagraf 5 mg: Each capsule contains 5 mg tacrolimus (as monohydrate).

להלן עדכונים בעלון לרופא (טקסט מסומן ירוק משמעותו עדכון טקסט אדום עם קו חוצה משמעותו מחיקה (מחיקה)):

[...]


4.2 Posology and method of administration

Advagraf is a once-a-day oral formulation of tacrolimus. Advagraf therapy requires careful monitoring by adequately qualified and equipped personnel. This medicinal product should only be prescribed, and changes in immunosuppressive therapy initiated, by physicians experienced in immunosuppressive therapy and the management of transplant patients.

Different oral formulations of tacrolimus should not be substituted without clinical supervision.
Inadvertent, unintentional or unsupervised switching **of immediate or prolonged release formulations between different oral formulations** of tacrolimus **with different release characteristics** is unsafe. This can lead to graft rejection or increased incidence of adverse reactions, including under- or overimmunosuppression, due to clinically relevant differences in systemic exposure to tacrolimus. Patients should be maintained on a single formulation of tacrolimus with the corresponding daily dosing regimen; alterations in formulation or regimen should only take place under the close supervision of a transplant specialist (see sections 4.4 and 4.8). Following conversion to any alternative formulation, therapeutic drug monitoring must be performed and dose adjustments made to ensure that systemic exposure to tacrolimus is maintained.

[...]

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלו מודפס על ידי פניה לבעל הרישום אסטלס פארמה אינטרנשונל ב.י.ו., ת.ד. 11458, ראש העין.

בברכה

גל פרידמן
רוקח ממונה