

פרסום עדכון בעלוני התכשיר: Forxiga Film-Coated Tablets**הרכב:**

Dapagliflozin 5mg, 10mg

חברת אסטרזניקה ישראל מבקשת להודיע על עדכון נוסח התוויה ועדכון העלונים בהתאם להוראות משרד הבריאות בתאריך אפריל 2022.

התוויה:

Forxiga is indicated

In adults aged 18 years and older for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

✚ as monotherapy when metformin is considered inappropriate due to intolerance.

✚ in addition to other medicinal products for the treatment of type 2 diabetes.

For study results with respect to combination of therapies, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.

to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.

to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Limitations of Use

✚ FORXIGA is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. FORXIGA is not expected to be effective in these populations.

העדכונים המהותיים בעלון לרופא הינם:**Posology****Type 2 Diabetes Mellitus**

When dapagliflozin is used to treat T2DM in combination with insulin or an insulin secretagogue, such as a sulphonylurea, a lower dose of insulin or insulin secretagogue may be considered to reduce the risk of hypoglycaemia (see sections 4.5 and 4.8).

See Table 1 for dosage recommendations based on estimated glomerular filtration rate (eGFR).

Table 1. Recommended Dosage

eGFR (mL/min/1.73 m ²)	Recommended Dose
eGFR 45 or greater	For all indications, the recommended starting dose is 10 mg orally once daily.
eGFR 25 to less than 45	For the treatment of insufficiently controlled type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m ² , Forxiga is not recommended*. For all other indications, the recommended starting dose is 10 mg orally once daily. 10mg orally once daily*
eGFR less than 25	Initiation is not recommended, however patients may continue 10 mg orally once daily to reduce the risk of eGFR decline, ESKD, CV death and hHF.
On dialysis	Contraindicated.

** FORXIGA is not recommended for the treatment of insufficiently controlled type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m². FORXIGA is likely to be ineffective in this setting based upon its mechanism of action.*

hHF: hospitalization for heart failure, CV: Cardiovascular, ESKD: End Stage Kidney Disease.

אין עדכונים בעלון לצרכן.



מקרא לעדכונים המסומנים:
תוספת טקסט מהותי מסומנת בצבע אדום.
מחיקת טקסט מסומנת בקו חוצה בצבע כחול.

העלוניים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

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