

יולי 2022

רופא/ה נכבד/ה רוקח/ת נכבד/ה,

## <u>הריני להודיעכם כי העלון לרופא של התכשיר עודכן:</u>

Givlaari

גיבלרי

## **SOLUTION FOR INJECTION**

הרכב:

Each mL of solution contains givosiran sodium equivalent to 189 mg givosiran

התוויה:

Givlaari is indicated for the treatment of acute hepatic porphyria (AHP) in adults and adolescents aged 12 years and older.

להלן העדכון בעלון לרופא:

## 4.4 Special warnings and precautions for use

Blood homocysteine increased

Blood homocysteine levels may be increased in patients with AHP, vitamin deficiencies, or chronic kidney disease. During treatment with givosiran, increases in blood homocysteine levels have been observed compared to levels before treatment (see section 4.8). The clinical relevance of the elevations in blood homocysteine during treatment with givosiran is unknown. However, homocysteine elevations have been previously associated with an increased risk of thromboembolic events.

Measurement of blood homocysteine levels prior to initiating treatment and monitoring for changes during treatment with givosiran is recommended. In patients with elevated homocysteine levels, homocysteine-lowering therapy can be considered.

## 4.8 Undesirable effects

**Table 1: Adverse reactions** 

System organ class	Adverse reaction	Frequency
General disorders and administration site conditions	Injection site reactions	Very common
	Fatigue	Very common
Investigations	Blood homocysteine increased <sup>c</sup>	<u>Common</u>

העלון לרופא נמצא בקישור וכן מפורסם במאגר התרופות באתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה.

מדיסון פארמה בע"מ

