הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 8.6.2015

שם תכשיר באנגלית **Januet 50mg/500 mg, 50 mg/850 mg, 50 mg/1000 mg Tablets**

מספר הרישום 31706, 31902, 31705

שם בעל הרישום. Merck Sharp & Dohme (Israel – 1996) Company Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Hypersensitivity to metformin hydrochloride[1].		**4 CONTRAINDICATIONS**
Therefore, JANUET is contraindicated in patients with renal impairment.[1] Before initiation of JANUET and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal dysfunction is anticipated (e.g., elderly), renal function should be assessed more frequently and JANUET discontinued if evidence of renal impairment is present.	Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive JANUET	**5 WARNINGS AND PRECAUTIONS** **5.4 Assessment of Renal Function**
pruritus		**6 ADVERSE REACTIONS** ***6.2 Postmarketing Experience***
7.1 Carbonic Anhydrase Inhibitors Topiramate or other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) frequently decrease serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Concomitant use of these drugs may induce metabolic acidosis. Use these drugs with caution in patients treated with JANUET, as the risk of lactic acidosis may increase[1].		**7 DRUG INTERACTIONS**
Table 7: Effect of Coadministered Drugs on Systemic Exposure of Metformin[1] Carbonic anhydrase inhibitors may cause metabolic acidosis: use with caution. *[See Warnings and Precautions (5.1) and Drug Interactions (7.1).]*		**12 CLINICAL PHARMACOLOGY** **12.3 Pharmacokinetics**

Coadministered Drug	Dose of Coadministered Drug*	Dose of Metformin*	Geometric Mean Ratio (ratio with/without coadministered drug) No Effect = 1.00		
				AUC†	C_{max}
Topiramate	100 mg¶	500 mg¶	Metformin	1.25¶	1.17