הודעה על החמרה (מידע בטיחות)

תאריך: 24.12.12

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

מספר רישום: 31706, 31902, 31705

שם בעל הרישום: Merck, Sharp & Dohme (Israel-1996) Company Ltd.

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Warnings and Precautions	**5.4 Assessment of Renal Function** Metformin and sitagliptin are known to be substantially excreted by the kidney. The risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive JANUET. In the elderly, JANUET should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging can be associated with reduced renal function. *[See Warnings and Precautions (5.1) and Use in Specific Populations (8.5).]* Before initiation of therapy with 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, particularly in elderly patients, renal function should be assessed more frequently and JANUET discontinued if evidence of renal impairment is present.	**5.4 Assessment of Renal Function** Metformin and sitagliptin are known to be substantially excreted by the kidney. The risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive JANUET. In the elderly, JANUET should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging can be associated with reduced renal function. *[See Warnings and Precautions (5.1); Use in Specific Populations (8.5).]* There have been postmarketing reports of worsening renal function, including acute renal failure, sometimes requiring dialysis. Before initiation of therapy with 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, particularly in elderly patients, renal function should be assessed more frequently and JANUET discontinued if evidence of renal impairment is present.
Warnings and Precautions	**5.14 Hypersensitivity Reactions** There have been postmarketing reports of serious hypersensitivity reactions in patients treated with sitagliptin, one of the components of JANUET. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including	**5.14 Hypersensitivity Reactions** There have been postmarketing reports of serious hypersensitivity reactions in patients treated with sitagliptin, one of the components of JANUET. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions

including Stevens-Johnson syndrome. Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUET, assess for other potential causes for the event, and institute alternative treatment for diabetes. *[See Adverse Reactions (6.2).]* Angiooedema has also been reported with other dipeptidyl peptidase-4 (DPP-4) inhibitors. Use caution in a patient with a history of angioedema with another DPP-4 inhibitor because it is unknown whether such patients will be predisposed to angioedema with JANUET.	Stevens-Johnson syndrome. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Onset of these reactions occurred within the first 3 months after initiation of treatment with sitagliptin, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUET, assess for other potential causes for the event, and institute alternative treatment for diabetes. *[See Adverse Reactions (6.2).]*	
6.2 Postmarketing Experience Additional adverse reactions have been identified during postapproval use of JANUET or sitagliptin, one of the components of JANUET. These reactions have been reported when JANUET or sitagliptin have been used alone and/or in combination with other antihyperglycemic agents. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, cutaneous vasculitis, and exfoliative skin conditions including Stevens-Johnson syndrome *[see Warnings and Precautions (5.14)];* upper respiratory tract infection; hepatic enzyme elevations; acute pancreatitis, including fatal and non-fatal hemorrhagic and necrotizing pancreatitis *[see Indications and Usage (1); Warnings and Precautions (5.2)]*; worsening renal function, including acute renal failure (sometimes requiring dialysis) *[see Warnings and Precautions (5.4)];* constipation; vomiting; headache; arthralgia; myalgia; pain in extremity; back pain.	**6.2 Postmarketing Experience** Additional adverse reactions have been identified during postapproval use of JANUET or sitagliptin, one of the components of JANUET. These reactions have been reported when JANUET or sitagliptin have been used alone and/or in combination with other antihyperglycemic agents. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria, cutaneous vasculitis, and exfoliative skin conditions including Stevens-Johnson syndrome *[see Warnings and Precautions (5.14)];* upper respiratory tract infection; hepatic enzyme elevations; acute pancreatitis, including fatal and non-fatal hemorrhagic and necrotizing pancreatitis *[see Limitations of Use (1); Warnings and Precautions (5.2)]*; worsening renal function, including acute renal failure (sometimes requiring dialysis); constipation; vomiting; headache.	**Post-Marketing Experience**

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פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
תופעות לוואי אפשריות (תחת תופעות לוואי חמורות)		**בעיות בכליות**, המצריכות לפעמים דיאליזה
תופעות לוואי אפשריות (תחת תופעות לוואי אחרות)		• כאב במפרק. • כאבי שרירים. • כאב ביד או ברגל. • כאב גב.