

הודעה על החמרה (מידע בטיחות)

תאריך: 19.3.13

שם תכשיר באנגלית: Januvia 25 mg, 50 mg, 100 mg Tablets

מספר רישום: 31554, 31555, 31556

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

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינויים המבוקש/ים

| טקסט חדש | טקסט נוכחי | פרק בעלון |
|--|--|--|
| <p>5.2 Renal Impairment</p> <p>Assessment of renal function is recommended prior to initiating JANUVIA and periodically thereafter. A dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD requiring hemodialysis or peritoneal dialysis. [See Dosage and Administration (2.2); Clinical Pharmacology (12.3).]</p> <p>Caution should be used to ensure that the correct dose of JANUVIA is prescribed for patients with moderate (creatinine clearance ≥ 30 to < 50 mL/min) or severe (creatinine clearance < 30 mL/min) renal impairment.</p> <p>There have been postmarketing reports of worsening renal function, including acute renal failure, sometimes requiring dialysis. A subset of these reports involved patients with renal insufficiency, some of whom were prescribed inappropriate doses of sitagliptin. A return to baseline levels of renal insufficiency has been observed with supportive treatment and discontinuation of potentially causative agents. Consideration can be given to cautiously reinitiating JANUVIA if another etiology is deemed likely to have precipitated the acute worsening of renal function.</p> <p>JANUVIA has not been found to be nephrotoxic in preclinical studies at clinically relevant doses, or in clinical trials.</p> | <p>5.2 Use in Patients with Renal Insufficiency</p> <p>A dosage adjustment is recommended in patients with moderate or severe renal insufficiency and in patients with ESRD requiring hemodialysis or peritoneal dialysis. [See Dosage and Administration (2.2); Clinical Pharmacology (12.3).]</p> | <p>Warnings and Precautions</p> |

| | | |
|--|--|---|
| <p>5.4 Hypersensitivity Reactions Onset of these reactions occurred within the first 3 months after initiation of treatment with JANUVIA, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUVIA, assess for other potential causes for the event, and institute alternative treatment for diabetes. <i>[See Adverse Reactions (6.2).]</i> Angioedema 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 JANUVIA.</p> | <p>5.4 Hypersensitivity Reactions There have been postmarketing reports of serious hypersensitivity reactions in patients treated with JANUVIA. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions including 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 JANUVIA, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUVIA, assess for other potential causes for the event, and institute alternative treatment for diabetes. <i>[See Adverse Reactions (6.2).]</i></p> | <p>Warnings and Precautions</p> |
| <p>6.2 Postmarketing Experience Additional adverse reactions have been identified during postapproval use of JANUVIA as monotherapy 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 <i>[see Warnings and Precautions (5.4)]</i>; hepatic enzyme elevations; acute pancreatitis, including fatal and non-fatal hemorrhagic and necrotizing pancreatitis <i>[see Indications and Usage (1.2); Warnings and Precautions (5.1)]</i>; worsening renal function, including acute renal failure (sometimes requiring dialysis) <i>[see Warnings and Precautions (5.2)]</i>; constipation; vomiting; headache; arthralgia; myalgia; pain in extremity; back pain.</p> | <p>6.2 Postmarketing Experience Additional adverse reactions have been identified during postapproval use of JANUVIA as monotherapy 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 <i>[see Warnings and Precautions (5.4)]</i>; hepatic enzyme elevations; acute pancreatitis, including fatal and non-fatal hemorrhagic and necrotizing pancreatitis <i>[see Limitations of Use (1.2); Warnings and Precautions (5.1)]</i>; Constipation; vomiting; headache.</p> | <p>Post-Marketing Experience</p> |

.....

הודעה על החמרה (מידע בטיחות)

תאריך: 19.3.13

שם תכשיר באנגלית: **Januvia 25 mg, 50 mg, 100 mg Tablets**

מספר רישום: 31554, 31555, 31556

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

השינויים בעלון מסומנים על רקע צהוב

בעלון לצרכן

| פרטים על השינויים המבוקשים | | |
|--|-----------------------|---|
| פרק בעלון | טקסט נוכחי | טקסט חדש |
| 2.2 אזהרות | סבלת בעבר מפנקראטיטיס | הינך סובל/סבלת בעבר מפנקראטיטיס |
| 3. איך תשתמש | — | הרופא שלך ישלח אותך לבדיקות דם מפעם לפעם על מנת לבדוק את תפקודי הכליות שלך |
| 4. תופעות לוואי אפשריות (תחת תופעות לוואי רציניות) | — | בעיות בכליות, המצריכות לפעמים דיאליזה. |
| 4. תופעות לוואי אפשריות (תחת תופעות לוואי נוספות) | — | <ul style="list-style-type: none"> • כאבי פרקים • כאבי שרירים • כאב בזרוע או ברגל • כאבי גב |
| | | |
| | | |
| | | |