הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: 6 אוקטובר 2015

שם תכשיר באנגלית ומספר הרישום Entyvio (153 58 34277 00)

שם בעל הרישום טקדה ישראל בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
NA	NA	**Indication**
NA	NA	**contraindications**
NA	NA	**Posology, dosage & administration**
Vedolizumab should be administered in a healthcare setting equipped to allow management of acute hypersensitivity reactions including anaphylaxis, if they occur. Appropriate monitoring and medical support measures should be available for immediate use when administering Vedolizumab. All patients should be observed continuously during each infusion. For the first two infusions, they should also be observed for approximately two hours following completion of the infusion for signs and symptoms of acute hypersensitivity reactions. For all subsequent infusions, patients should be observed for approximately one hour following	All patients should be observed continuously during each infusion. For the first two infusions, they should also be observed for approximately two hours following completion of the infusion for signs and symptoms of acute hypersensitivity reactions. For all subsequent infusions, patients should be observed for approximately one hour following completion of the	**Special Warnings and Special Precautions for Use**

<table>
<tr>
<td>completion of the infusion.

….</td>
<td>infusion.

….</td>
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</tr>
<tr>
<td>NA</td>
<td>NA</td>
<td>Interaction with Other Medicaments and Other Forms of Interaction</td>
</tr>
<tr>
<td>NA</td>
<td>NA</td>
<td>pregnancy Fertility, and Lactation</td>
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<tr>
<td>Vedolizumab has been studied in three placebo-controlled clinical trials in patients with ulcerative colitis (GEMINI I) or Crohn’s disease (GEMINI II and III). In two controlled studies (GEMINI I and II) involving 1,434 patients receiving vedolizumab 300 mg at Week 0, Week 2 and then every eight weeks or every four weeks from week 6 for up to 52 weeks, and 297 patients…….

Table 1. Adverse Reactions

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<tr><th>System Organ Class</th><th>Frequency</th><th>Adverse Reaction(s)</th></tr>
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<tr><td>Common</td><td>Muscle spasms, Back pain, Muscular weakness, Fatigue, Pain in the extremity</td></tr>
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מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק . יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 6 אוקטובר 2015