

תאריך: 6.11.2014.

שם תכשיר באנגלית ומספר הרישום:

Sandostatin 0.05 mg 047-03-25697-00

Sandostatin 0.1mg 047-01-25698-00

Sandostatin 0.2mg 047-02-25699-00

Sandostatin 0.5mg 107-13-27200-00

שם בעל הרישום: Novartis Pharma Services AG.

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות												
טקסט חדש	טקסט נוכחי	פרק בעלון										
<p>...</p> <p><b>Cardiovascular related events</b></p> <p>Uncommon – Cases of bradycardia have been reported. (frequency: common).</p> <p>...</p>	<p>...</p> <p><b>Cardiovascular related events</b></p> <p>Uncommon cases of bradycardia have been reported.</p> <p>...</p>	6 Warnings and precautions										
<p>...</p> <p><b>Glucose metabolism</b></p> <p>... Hypoglycemia has also been reported.</p>	<p>...</p> <p><b>Glucose metabolism</b></p> <p>...</p>	6 Warnings and precautions										
<p>...</p> <p><b>Table 7.1 Adverse drug reactions reported in clinical studies</b></p> <p>...</p> <table border="1"> <tr> <th colspan="2"><u>General disorders and administration site conditions</u></th> </tr> <tr> <td>Very common:</td> <td>Injection site localized pain reaction.</td> </tr> <tr> <td>Common:</td> <td>Asthenia</td> </tr> </table> <p>...</p>	<u>General disorders and administration site conditions</u>		Very common:	Injection site localized pain reaction.	Common:	Asthenia	<p>...</p> <p><b>Table 1 Adverse drug reactions reported in clinical studies</b></p> <p>....</p> <table border="1"> <tr> <th colspan="2"><b>General disorders and administration site disorders:</b></th> </tr> <tr> <td>Very common:</td> <td>Injection site localized pain</td> </tr> </table> <p>....</p>	<b>General disorders and administration site disorders:</b>		Very common:	Injection site localized pain	7 Adverse drug reactions
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<p>...</p> <p><u>Dose adjustment of medicinal products such as beta blockers, calcium channel blockers, or agents to control fluid and electrolyte balance may be necessary when Sandostatin LAR is administered concomitantly (see section 6 Warnings</u></p>	<p>...</p>	8 Interactions										

ההחמרות המבוקשות

and precautions).

Dose adjustments of insulin and antidiabetic medicinal products may be required when Sandostatin LAR is administered concomitantly (see section 6 Warnings and precautions).

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מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות **על רקע צהוב**. שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 6 בנובמבר, 2014