

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

אושר – 5.16

תאריך 05.2016

שם תכשיר באנגלית ומספר הרישום: **Influvac, 033-66-22645-00**

שם בעל הרישום **אבוט מעבדות רפואיות בע"מ**

**טופס זה מיועד לפרוט החמרות בלבד !**

החמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p><b>4. CLINICAL PARTICULARS</b>  <b>4.1. Therapeutic indications</b>                      Prophylaxis of influenza, especially those who run an increased risk of associated complications.</p> <p>Influvac is indicated in adults and children from 6 months of age.                      The use of Influvac should be based on official recommendations.</p>	<p><b>3. CLINICAL PARTICULARS</b>  <b>3.1 Therapeutic indications</b>                      Prophylaxis of influenza; especially those who run an increased risk of associated complications.</p> <p>Influvac is indicated in adults and children from 6 months of age.                      The use of Influvac should be based on official recommendations.                      Vaccination is particularly recommended for the following categories of patients, depending on national immunization policies:</p> <ul style="list-style-type: none"> <li>- Persons aged <math>\geq 65</math> years, regardless their health condition.</li> <li>- Adults and children with chronic disorders of the pulmonary or cardiovascular systems, including asthma.</li> <li>- Adults and children with chronic metabolic diseases such as diabetes mellitus.</li> <li>- Adults and children with chronic renal dysfunction.</li> <li>- Adults and children with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.</li> <li>- Children and teenagers (6 months – 18 years) who receive long-term acetylsalicylic acid containing medication, and might therefore be at risk for developing Reye's syndrome following an influenza infection.</li> </ul>	<p>Indication</p>

## ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
<p><b>4.4. Special warnings and precautions for use</b> As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.</p> <p>Influvac should under no circumstances be administered intravascularly.</p> <p><b>Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, a vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbances, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</b></p> <p>Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.</p> <p>Interference with serological testing: see section 4.5.</p>	<p><b>3.4 Special warnings and precautions for use</b> As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.</p> <p>Influvac should under no circumstances be administered intravascularly.</p> <p>Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.</p> <p>Interference with serological testing: see section 3.5.</p>	<p><b>Special Warnings and Special Precautions for Use</b></p>

מצי"ב העלון, שבו מסומנות ההחמרות המבוקשות **על רקע צהוב**. שינויים שאינם בגדר החמרות סומנו (בעלון) בטקסט **ירוק** או **אדום**.  
הועבר בדואר אלקטרוני בתאריך \_\_\_\_\_

