

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 3102.50)

תאריך : 3-Nov-2013

שם תכשיר באנגלית ומספר הרישום :

Abbosynagis 50 mg, 119-63-30030-00  
Abbosynagis 100 mg, 119-01-29909-00

שם בעל הרישום : AbbVie Biopharmaceuticals Ltd.

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות מסומנות על רקע צהוב

## ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון																								
<p>Palivizumab may interfere with immune-based RSV diagnostic tests, such as some antigen detection based assays. In addition, palivizumab inhibits virus replication in cell culture and, therefore, may also interfere with viral culture assays. Palivizumab does not interfere with reverse transcriptase polymerase chain reaction-based assays. Assay interference could lead to false-negative RSV diagnostic test results. Therefore, diagnostic test results, when obtained, should be used in conjunction with clinical findings to guide medical decisions.</p>	N/A	<p>4. CLINICAL PARTICULARS</p> <p>4.5 Interaction with other medicinal products and other forms of interaction</p>																								
<table border="1"> <thead> <tr> <th colspan="3">Undesirable effects in clinical studies* and post-marketing reports in paediatric patients</th></tr> <tr> <th>MedDRA System Organ Class</th><th>Frequency</th><th>ADR</th></tr> </thead> <tbody> <tr> <td>Skin and subcutaneous tissue disorders</td><td>Very common</td><td>Rash</td></tr> <tr> <td>General disorders and administrative site conditions</td><td>Very common</td><td>Pyrexia</td></tr> <tr> <td>Blood and lymphatic system disorders</td><td>Uncommon</td><td>Thrombocytopenia<sup>#</sup></td></tr> <tr> <td>Nervous system disorders</td><td>Uncommon</td><td>Convulsion<sup>#</sup></td></tr> <tr> <td>Respiratory, thoracic and mediastinal disorders</td><td>Common</td><td>Apnoea<sup>#</sup></td></tr> <tr> <td>Skin and subcutaneous tissue disorders</td><td>Uncommon</td><td>Urticaria<sup>#</sup></td></tr> </tbody> </table>	Undesirable effects in clinical studies* and post-marketing reports in paediatric patients			MedDRA System Organ Class	Frequency	ADR	Skin and subcutaneous tissue disorders	Very common	Rash	General disorders and administrative site conditions	Very common	Pyrexia	Blood and lymphatic system disorders	Uncommon	Thrombocytopenia <sup>#</sup>	Nervous system disorders	Uncommon	Convulsion <sup>#</sup>	Respiratory, thoracic and mediastinal disorders	Common	Apnoea <sup>#</sup>	Skin and subcutaneous tissue disorders	Uncommon	Urticaria <sup>#</sup>	<p>ישנו שינוי פורמט כללי בתופעות הלוואי.</p> <p style="text-align: right;">בטקסט הנוכחי:</p> <p>Skin and subcutaneous tissue disorders – Rash is an Uncommon undesirable effect in prophylactic clinical studies with premature and bronchopulmonary dysplasia paediatric populations and in the prophylactic paediatric congenital Heart Disease Clinical Study.</p> <p>General disorders and administration site conditions – Fever is a Common undesirable effect in prophylactic clinical studies with premature and bronchopulmonary dysplasia paediatric populations and in the prophylactic paediatric congenital Heart Disease Clinical Study.</p> <p><u>Post-marketing experience:</u></p> <p>Blood and lymphatic system disorders: thrombocytopenia</p> <p>Nervous system disorders: convulsion</p> <p>Respiratory, thoracic and mediastinal disorders: apnoea</p> <p>Skin and subcutaneous tissue</p>	<p>4. CLINICAL PARTICULARS</p> <p>4.8 Undesirable effects</p>
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