# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך 07.2014**

**שם תכשיר באנגלית ומספר הרישום:  
 Arzerra 100mg, Arzerra 1000mg (148-72-33501, 148-71-33508**

**שם בעל הרישום GlaxoSmithKline (ISRAEL) Ltd :**

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Posology and method of administration** | **-** | Monitoring  Patients should be closely monitored during administration of ofatumumab for the onset of infusion reactions, including cytokine release syndrome, particularly during the first infusion. |
| **Special warnings and precautions for use** | Infusion reactions  Ofatumumab has been associated with infusion reactions leading to temporary interruption of treatment or withdrawal of treatment. Pre-medications attenuate infusion reactions but these may still occur, predominantly during the first infusion. Infusion reactions may include anaphylactoid events, cardiac events, chills/rigors, cough, cytokine release syndrome, diarrhoea, dyspnoea, fatigue, flushing, hypertension, hypotension, nausea, pain, pyrexia, rash, and urticaria. Even with pre-medication, severe reactions, including cytokine release syndrome, have been reported following use of ofatumumab. In cases of severe infusion reaction, the infusion of Arzerra must be interrupted immediately and symptomatic treatment instituted (see section 4.2). | Infusion reactions  Intravenous ~~O~~ofatumumab has been associated with infusion reactions. These reactions may result in ~~leading to~~ temporary interruption ~~of treatment~~ or withdrawal of treatment. Pre-medications attenuate infusion reactions but these may still occur, predominantly during the first infusion. Infusion reactions may include, but are not limited to, anaphylactoid events, bronchospasm, cardiac events (eg. myocardial ischaemia / infarction, bradycardia), chills/rigors, cough, cytokine release syndrome, diarrhoea, dyspnoea, fatigue, flushing, hypertension, hypotension, nausea, pain, pulmonary oedema, pruritus, pyrexia, rash, and urticaria. In rare cases, these reactions may lead to death. Even with pre-medication, severe reactions, including cytokine release syndrome, have been reported following use of ofatumumab. In cases of severe infusion reaction, the infusion of Arzerra must be interrupted immediately and symptomatic treatment instituted (see section 4.2). |
| **Undesirable effects**  **Undesirable effects** |  | Cardiac disorders  UncommonBradycardia\* |
|  | Respiratory, thoracic and mediastinal disorders UncommonPulmonary oedema\* |
|  | \*These events are likely attributable to ofatumumab in the setting of an infusion reaction and typically occur after the start of infusion and within 24 hours after the completion of the infusion (see section 4.4). |
|  | *Postmarketing Experience*  The following adverse reactions have been identified during post-approval use of Arzerra. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.  Infusion-related Cardiac Events: Cardiac arrest.  Mucocutaneous Reactions: Stevens-Johnson syndrome, porphyria cutanea tarda. |

**מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.**

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.