# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך : 10-2014**

**שם תכשיר באנגלית ומספר הרישום: Zovirax I.V. (Reg.No.:034-33-21976)**

**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** |
| **Contraindications** | Aciclovir I.V. for Infusion is contraindicated in patients known to be previously hypersensitive to aciclovir or valaciclovir. | Zovirax I.V. is contra-indicated in patients known to be previously hypersensitive to aciclovir or valaciclovir, or to any of the excipients. |
| **Special Warnings and Special Precautions for Use** | ---------  **Formulation and strength**  The sodium ion content is approximately 26 mg per vial. | Adequate hydration should be maintained in patients given i.v. or high oral doses of aciclovir.  Intravenous doses should be given by infusion over one hour to avoid precipitation of aciclovir in the kidney; rapid or bolus injection should be avoided.  The risk of renal impairment is increased by use with other nephrotoxic drugs. Care is required if administering i.v. acyclovir with other nephrotoxic drugs.  **Formulation and strength**  This medicinal product contains 26mg, approx. 1,13mmol sodium per vial. To be taken into consideration by patients on a controlled sodium diet. |
| **Interaction with Other Medicaments and Other Forms of Interaction** | ---------  --------- | If **lithium** is administered concurrently with high dose aciclovir IV, the lithium serum concentration should be closely monitored because of the risk of lithium toxicity.  An experimental study on five male subjects indicates that concomitant therapy with aciclovir increases AUC of totally administered **theophylline** with approximately 50%. It is recommended to measure plasma concentrations during concomitant therapy with aciclovir. |
| **Adverse events** | Very rare: renal impairment, acute renal failure and renal pain.  Renal pain may be associated with renal failure | Very rare: renal impairment, acute renal failure and renal pain.  Renal pain may be associated with renal failure and crystalluria. |

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

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.