# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

**תאריך: 8 בספטמבר 2014**

**שם תכשיר באנגלית ומספר הרישום: Foscavir 24mg/ml No. 068-16-28118**

**שם בעל הרישום: טק-או-פארם-ליברה בע"מ**

טופס זה מיועד לפרוט ההחמרות בלבד !

| ההחמרות המבוקשות | | |
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| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **הוספת Black box** | | WARNING<br><br>RENAL IMPAIRMENT IS THE MAJOR TOXICITY OF FOSCAVIR. FREQUENT<br><br>MONITORING OF SERUM CREATININE, WITH DOSE ADJUSTMENT FOR<br><br>CHANGES IN RENAL FUNCTION, AND ADEQUATE HYDRATION WITH<br><br>ADMINISTRATION OF FOSCAVIR IS IMPERATIVE. (See ADMINISTRATION section;<br><br>Hydration.)<br><br>SEIZURES, RELATED TO ALTERATIONS IN PLASMA MINERALS AND<br><br>ELECTROLYTES, HAVE BEEN ASSOCIATED WITH FOSCAVIR TREATMENT.<br><br>THEREFORE, PATIENTS MUST BE CAREFULLY MONITORED FOR SUCH<br><br>CHANGES AND THEIR POTENTIAL SEQUELAE. MINERAL |

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| AND ELECTROLYTE<br><br>SUPPLEMENTATION MAY BE REQUIRED.<br><br>FOSCAVIR IS INDICATED FOR USE ONLY IN IMMUNOCOMPROMISED PATIENTS<br><br>WITH CMV RETINITIS (See INDICATIONS section). | | |
| | | **Contraindications** |
| | | **Posology, dosage & administration** |
| Due to the sodium content of Foscavir (240 micromoles (5.5 mg) of sodium per ml), it's use should be avoided when a saline load cannot be tolerated (e.g. in cardiomyopathy). This should also be taken into consideration by patients on a controlled sodium diet.<br><br>Seizures, related to alterations in plasma minerals and electrolytes, have been associated with Foscavir treatment. Therefore, patients must be carefully monitored for such changes and their potential sequelae. Mineral and electrolyte supplementation may be required.<br><br>Should patients experience extremity paresthesia or nausea, it is recommended to reduce the speed of infusion. | - | **Special Warnings and Special Precautions for Use** |
| Since Foscavir can impair renal function, additive toxicity may occur when used in combination with other nephrotoxic drugs such as aminoglycosides, amphotericin B, cyclosporin A, acyclovir, methotrexate and tacrolymus. Moreover, since Foscavir can reduce serum levels of ionised calcium, extreme caution is advised when used concurrently with other drugs known to influence serum calcium levels, like i.v. pentamidine. Renal impairment and symptomatic hypocalcaemia (Trousseau's and Chvostek's signs) have been observed during concurrent | Since Foscavir can impair renal function, additive toxicity may occur when used in combination with other nephrotoxic drugs such as aminoglycoside antibiotics, amphotericin B and cyclosporin A. Moreover, since Foscavir can reduce serum levels of ionised calcium, extreme caution is advised when used concurrently with other drugs known to influence serum calcium levels, like i.v. pentamidine. Renal impairment and symptomatic hypocalcaemia (Trousseau's and Chvostek's signs) have been observed during concurrent treatment with | **Interaction with Other Medicaments and Other Forms of Interaction** |

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| treatment with Foscavir and i.v. pentamidine. Abnormal renal function has been reported in connection with the use of Foscavir in combination with ritonavir and/or saquinavir. | Foscavir and i.v. pentamidine. Abnormal renal function has been reported in connection with the use of foscarnet in combination with protease inhibitors associated with impaired renal function e.g. ritonavir and saquinavir.<br><br>The elimination of Foscavir may be impaired by drugs which inhibit renal tubular secretion.<br><br>There is no evidence of an increased myelotoxicity when foscarnet is used in combination with zidovudine (AZT). | |
| Foscavir is contraindicated in pregnancy.<br><br>Breastfeeding should be discontinued before starting Foscavir treatment. | <u>Fertility</u><br><br>There are no data available regarding the influence of Foscavir on fertility.<br><br>No effects on fertility were observed in animal studies (see section 5.3).<br><br>Women of childbearing potential / contraception in males and females<br><br>Women capable of childbearing should use effective contraception methods during Foscavir therapy.<br><br>Men treated with Foscavir should not father a child during or up to 6 months after therapy.<br><br><u>Pregnancy</u><br><br>There are no or limited amount of data from the use of foscarnet in pregnant women.<br><br>Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).<br><br>Foscavir is not recommended during pregnancy.<br><br><u>Lactation</u><br><br>There is insufficient information | **Fertility, Pregnancy and Lactation** |

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| | on the excretion of foscarnet in human milk.<br><br>Available pharmacodynamic/toxicological data in animals have shown excretion of foscarnet in milk (for details see section 5.3).<br><br>A risk to the newborns/infants cannot be excluded.<br><br>Foscavir should not be used during breast-feeding.<br><br>A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Foscavir therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. | |
| **תופעות לוואי חדשות:**<br><br>Anemia (very common)<br><br>Oesphageal ulcercaion, renal tubular acidosis, Crystal Nephropathy (frequency unknown)<br><br>Neutropenia Pancreatits, Pruritis, Myalgia (common)<br><br>Amylase increased, blood creatinine phosphokinase increased (uncommon) | **עליה בתדירות תופעות לוואי**<br><br>Neutropenia, Pancreatits, Pruritis, Myalgia (unknown)<br><br>Amylase increased, blood creatinine phosphokinase increased (unknown) | **Adverse events** |
| From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C. | | **Storage** |

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