# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך: ‏08 ספטמבר 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 !

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **הוספת Black box** |  | WARNING  RENAL IMPAIRMENT IS THE MAJOR TOXICITY OF FOSCAVIR. FREQUENT  MONITORING OF SERUM CREATININE, WITH DOSE ADJUSTMENT FOR  CHANGES IN RENAL FUNCTION, AND ADEQUATE HYDRATION WITH  ADMINISTRATION OF FOSCAVIR IS IMPERATIVE. (See ADMINISTRATION s ection;  Hydration.)  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.  FOSCAVIR IS INDICATED FOR USE ONLY IN IMMUNOCOMPROMISED PATIENTS  WITH CMV RETINITIS (See INDICATIONS s ection). |
| **contraindications** |  |  |
| **Posology, dosage & administration** |  |  |
| **Special Warnings and Special Precautions for Use** | **~~-~~** | 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.  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.  Should patients experience extremity paresthesia or nausea, it is recommended to reduce the speed of infusion. |
| **Interaction with Other Medicaments and Other Forms of Interaction** | 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 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.  The elimination of Foscavir may be impaired by drugs which inhibit renal tubular secretion.  There is no evidence of an increased myelotoxicity when foscarnet is used in combination with zidovudine (AZT). | 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 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. |
| **Fertility, pregnancy and Lactation** | Fertility  There are no data available regarding the influence of Foscavir on fertility.  No effects on fertility were observed in animal studies (see section 5.3).  Women of childbearing potential / contraception in males and females  Women capable of childbearing should use effective contraception methods during Foscavir therapy.  Men treated with Foscavir should not father a child during or up to 6 months after therapy.  Pregnancy  There are no or limited amount of data from the use of foscarnet in pregnant women.  Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).  Foscavir is not recommended during pregnancy.  Lactation  There is insufficient information on the excretion of foscarnet in human milk.  Available pharmacodynamic/toxicological data in animals have shown excretion of foscarnet in milk (for details see section 5.3).  A risk to the newborns/infants cannot be excluded.  Foscavir should not be used during breast-feeding.  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. | Foscavir is contraindicated in pregnancy.  Breastfeeding should be discontinued before starting Foscavir treatment. |
| **Adverse events** | **עליה בתדירות תופעות לוואי**  Neutropenia, Pancreatits, Pruritis, Myalgia (unknown)  Amylase increased, blood creatinine phosphokinase increased (unknown) | **תופעות לוואי חדשות:**  Anemia (very common)  Oesphageal ulcercaion, renal tubular acidosis, Crystal Nephropathy (frequency unknown)  Neutropenia Pancreatits, Pruritis, Myalgia (common)  Amylase increased, blood creatinine phosphokinase increased (uncommon) |
| **Storage** |  | 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. |

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