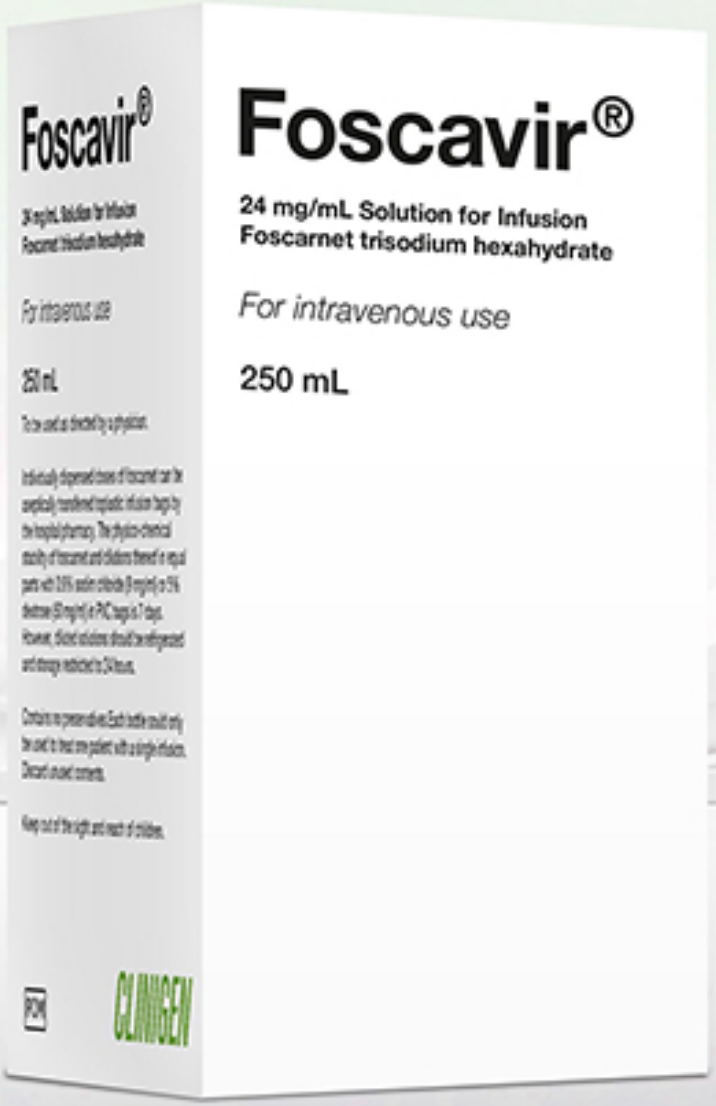
Foscavir®

6 g/250 ml, solution for infusion



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FOSCAVIR 6 g/250 ml, solution for infusion - Brief summary of product characteristics.
FOSCAVIR 6 g/250 ml, solution for infusion. Foscarnet sodium hexahydrate 6 g, for 250 ml of solution. Clear and colorless solution. **Therapeutic indications:** FOSCAVIR is indicated for the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS). Combination therapy with FOSCAVIR and ganciclovir is indicated for patients who have relapsed after monotherapy with either drug. SAFETY AND EFFICACY OF FOSCAVIR HAVE NOT BEEN ESTABLISHED FOR TREATMENT OF OTHER CMV INFECTIONS (e.g., PNEUMONITIS, GASTROENTERITIS); CONGENITAL OR NEONATAL CMV DISEASE; OR NONIMMUNOCOMPROMISED INDIVIDUALS. FOSCAVIR is indicated for the treatment of acyclovir-resistant mucocutaneous HSV infections in immunocompromised patients. SAFETY AND EFFICACY OF FOSCAVIR HAVE NOT BEEN ESTABLISHED FOR TREATMENT OF OTHER HSV INFECTIONS (e.g., RETINITIS, ENCEPHALITIS); CONGENITAL OR NEONATAL HSV DISEASE; OR HSV IN NONIMMUNOCOMPROMISED INDIVIDUALS. **Dosage:** It is imperative to adapt the following dosages to the state of renal function. It is imperative to combine treatment with hydration by infusion. Adults: Induction Treatment The recommended initial dose of FOSCAVIR for patients with normal renal function is: For CMV retinitis patients, either 90 mg/kg (1-1/2 to 2 hour infusion) every twelve hours or 60 mg/kg (minimum one hour infusion) every eight hours over 2-3 weeks depending on clinical response. For acyclovir-resistant HSV patients, 40 mg/kg (minimum one hour infusion) either every 8 or 12 hours for 2-3 weeks or until healed. Maintenance Treatment Following induction treatment the recommended maintenance dose of FOSCAVIR for CMV retinitis is 90 mg/kg/day to 120 mg/kg/day (individualized for renal function) given as an intravenous infusion over 2 hours. Because the superiority of the 120 mg/kg/day has not been established in controlled trials, and given the likely relationship of higher plasma foscarnet levels to toxicity, it is recommended that most patients be started on maintenance treatment with a dose of 90 mg/kg/day. Escalation to 120 mg/kg/day may be considered should early reinduction be required because of retinitis progression. Some patients who show excellent tolerance to FOSCAVIR may benefit from initiation of maintenance treatment at 120 mg/kg/day earlier in their treatment. **Caution:** Do not administer foscarnet as a rapid intravenous injection. Hydration: Attention is drawn to the importance of preventing renal toxicity of foscarnet by adequately hydrating patients. Hypersensitivity to the active substance or any of the excipients. Electrolytes, particularly calcium and magnesium, will be assessed before and during treatment with Foscavir and any deficiencies detected will be corrected. Foscarnet has been associated with cases of QT interval prolongation and more rarely with cases of torsade de pointes. Foscavir is excreted in significant concentrations in the urine and may be associated with significant genital irritation and/or ulceration. If patients experience significant nausea or extreme paresthesia, it is recommended to reduce the infusion speed. Since Foscavir may affect renal function, additive toxicity may occur when used concomitantly with other nephrotoxic drugs such as aminoglycosides, amphoreticin B, cyclosporin A, acyclovir, methotrexate, and tacrolimus. There is no pharmacokinetic interaction with Zidovudine (AZT), ganciclovir, didanosine (ddI), zalcitabine (ddC) or probenecid. Foscavir is not recommended during pregnancy. A risk to newborns/infants cannot be ruled out. Foscavir should not be used during breastfeeding. Women of childbearing potential should use effective methods of contraception during Foscavir treatment. Foscavir has a moderate influence on the ability to drive and use machines. Adverse effects; Very common (≥1/10), Anemia, granulocytopenia, loss of appetite, hypokalemia, hypomagnesemia, hypocalcemia, dizziness, headache, paresthesia, diarrhea, nausea, vomiting, asthenia, chills, fatigue, pyrexia. **Healthcare professionals report any suspected adverse reactions via the national reporting system:** National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: www.signalement-sante.gouv.fr. Overdoses have been reported when using Foscavir with the highest dose being 20 times the recommended dose. Hemodialysis by increasing the elimination of Foscavir may be beneficial in relevant cases. Antivirals for systemic use; direct-acting antivirals; phosphonic acid derivatives, **ATC code:** J05A D01. **The duration of the conversation:** Unopened: 2 years. After opening: the product must be used immediately. Before opening: Store at a temperature not exceeding 30°C. Do not refrigerate. CLINIGEN HEALTHCARE B.V. SCHIPHOL BOULEVARD 359 WTC SCHIPHOL AIRPORT D TOWER 11TH FLOOR 1118BJ SCHIPHOL NETHERLANDS 8. AUTHORITY NUMBER(S) MARKETING STATION 34009 346 445 0 4.

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