Prescribing Information
Fomicyt™ (Fosfomycin) 40mg/ml powder for solution for infusion. 2g and 4g presentations.
Consult the Summary of Product Characteristics for the full information.
Name and active ingredients: Fomicyt 40mg/ml powder for solution for infusion. One ml of reconstituted solution contains 40mg fosfomycin. Fomicyt 2g presentation: each vial with 2.69g of powder contains 2.64g disodium fosfomycin, corresponding to 2g fosfomycin and 0.64g sodium, for reconstitution in 50ml of solvent. Fomicyt 4g presentation: each vial with 5.38g of powder contains 5.28g disodium fosfomycin, corresponding to 4g fosfomycin and 1.28g sodium, for reconstitution in 100ml of solvent. **Indications:** Treatment in adults & children including neonates: Osteomyelitis, complicated urinary tract infections, nosocomial lower respiratory tract infections, bacterial meningitis, bacteraemia that occurs in association with, or is suspected to be associated with, any of these infections. Fomicyt should be used only when it is considered inappropriate to use antibacterial agents that are commonly recommended for the initial treatment of the infections listed, or when these agents have failed to demonstrate efficacy. Consideration should be given to official guidance on the appropriate use of antibacterial agents. **Dosage and administration:** Daily dose is determined based on the indication, severity and site of the infection, susceptibility of the pathogen(s) to fosfomycin and the estimated creatinine clearance. In children, it is also determined by age and body weight. For adults and adolescents ≥12 years, >40kg and with normal renal function (creatinine clearance >80ml/min): Osteomyelitis 12-24g in 2-3 divided doses, complicated urinary tract infection 12-16g in 2-3 divided doses, nosocomial lower respiratory tract infection 12-24g in 2-3 divided doses, bacterial meningitis 16-24g in 3-4 divided doses. Individual doses must not exceed 8g. Dose reductions in patients with renal impairment are required. Paediatric population; Dose recommendations are based on very limited data. Neonates, infants and children <12 years of age (<40kg) the dosage should be based on age and body weight. Method of administration: Intravenous infusion only. The solvent must be water for Injections, 5% or 10% Glucose Infusion. Fomicyt 2g should be dissolved in 50ml of solvent and given over at least 15 minutes, Fomicyt 4g should be dissolved in 100ml solvent and given over at least 30 minutes. **Contraindications:** Hypersensitivity to fosfomycin, or to any of the excipients. **Special warnings and precautions:** Consideration should be given to co-administering Fomicyt with another antibacterial agent. Caution advised in patients with cardiac insufficiency, hypertension, hyperaldosteronism, hypernatraemia or pulmonary oedema. One vial of Fomicyt 2g contains 28mmol (640mg) sodium. One vial of Fomciyt 4g contains 56mmol (1280mg) sodium. A low-sodium diet is recommended during treatment. Potassium substitution may be necessary in some cases. Serum electrolyte levels and water balance must be monitored. Acute, potentially life-threatening hypersensitivity reactions (anaphylactic shock) may occur in very rare cases. Antibacterial agent-associated colitis and pseudo-membranous colitis have been reported. It is important to consider this diagnosis in patients presenting with diarrhoea during or subsequent to administration of Fomicyt. **Interactions:** No drug-drug interaction studies have been performed with Fomicyt. No clinically relevant pharmacological interactions between fosfomycin and other agents have been reported. In-vitro tests have shown that the combination of fosfomycin with a β-lactam antibiotic such as penicillin, ampicillin, cefazolin or the class of carbapenems, usually shows an additive to synergistic effect. The same applies to the combination of fosfomycin with most anti-staphylococcal (linezolid, quinupristin/dalfopristin, moxifloxacin) agents in the treatment of staphylococcal infections. The combination of fosfomycin with aminoglycosides was predominantly indifferent to additive effects. **Undesirable effects (see SmPC for full details):** *Common:* Retching, stomach ache, injection site phlebitis. *Uncommon:* decreased appetite, hypernatraemia and/or hypokalaemia, oedema, dysgeusia, headache, vertigo, dyspnea, nausea, vomiting, diarrhoea, rash, fatigue, transient increases in blood alkaline phosphatase, aspartate amino transferase and alanine aminotransferase. *Rare:* aplastic anaemia, eosinophilia. *Very rare:* anaphylactic shock, visual impairment, fatty liver (reversible on withdrawal). Unknown frequency: Agranulocytosis, granulocytopenia, leucopenia, pancytopenia, thrombocytopenia, neutropenia, confusion, tachycardia, asthmatic attack, pseudomembranous colitis, hepatitis, cholestatic hepatitis, icterus, angioedema, facial oedema, pruritus, urticaria. **Legal classification:** POM. **Pack size:** 100ml clear glass vial with rubber stopper and pull off cap containing 2g or 4g. Packs of 10. **MA number:** PL15011/0014. **Basic NHS cost:** Fomicyt 2g: £150.00, Fomicyt 4g: £300.00. **Distributed by:** Nordic Pharma Limited, Unit 3, Commerce Park, Brunel Road, Theale, Reading, Berkshire, RG7 4AB. **Date of Preparation:** January 2017.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Nordic Pharma on 0800 121 8924

Fomicyt® IV
Fosfomycin
For difficult to treat bacterial infections

NORDIC PHARMA