

Abbreviated Prescribing Information.

Nitrofurantoin Mercury Pharma 100 mg prolonged-release capsules. Consult the Summary of Product Characteristics (SmPC) before prescribing. Additional information is available on request. **Presentations:** Each modified release, hard gelatinous capsule contains 100 mg of nitrofurantoin in the form of nitrofurantoin macrocrystals and nitrofurantoin monohydrate. **Indication:** *In adults, children, and infants over 12 years of age:* Treatment of and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections or pyelitis either spontaneous or following surgical procedures. Nitrofurantoin is specifically indicated for the treatment of infections when due to susceptible strains of *Escherichia coli*, *Enterococci*, *Staphylococci*, *Citrobacter*, *Klebsiella*, and *Enterobacter*. All strains of *Pseudomonas* and most strains of *Proteus* and *Serratia* are resistant. **Dose:** *Acute or recurrent uncomplicated UTI and pyelitis:* 100 mg twice daily for 7 days. *Surgical Prophylaxis:* 100 mg twice daily on the day of procedure and 3 days thereafter. **Special populations:** *Elderly patients:* Recommended dosing for elderly is the same as that for normal adult patients if there is no significant renal impairment. *Renal impairment:* Contraindicated in patients with renal dysfunction and in patients with an eGFR below of less than 45ml/minute. *Children under 12 years:* Not suitable for children under 12 years. **Administration:** For oral use. The dose should be taken with food or milk. **Contraindications:** Hypersensitivity to active substance, other nitrofurans or any excipients, acute porphyria, G6PD deficiency, patients suffering from renal dysfunction with an eGFR below 45ml/minute, infants under three months of age, pregnant patients at term. **Special warnings and precautions for use:** Not effective for treatment of parenchymal infections of unilaterally functioning kidney. To be used with caution in patients with pulmonary disease, hepatic dysfunction, neurological disorder, allergic diathesis, anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions, Vitamin B deficiency. To be used with caution as short-course therapy only for treatment of uncomplicated lower urinary tract infections in patients with eGFR between 30-44 ml/min. Treatment should be stopped at the first sign of neural involvement (paraesthesiae). Peripheral neuropathy and susceptibility to peripheral neuropathy may become severe or irreversible and may be life threatening. Treatment to be discontinued immediately if any acute, subacute and chronic pulmonary reactions are observed and at any signs of haemolytic in patients with suspected glucose-6-phosphate dehydrogenase deficiency. Chronic pulmonary reactions can develop insidiously and may occur commonly in elderly patients. Close monitoring of pulmonary conditions of patients receiving long-term therapy is warranted, especially in elderly. Patients are susceptible to false -positive urinary glucose. Hepatic reactions occur rarely. Fatalities have been reported. Onset of chronic active hepatitis is insidious, and patients should be monitored periodically for changes in biochemical tests that would indicate liver injury. If hepatitis occur, drug should be withdrawn immediately and appropriate measures to be taken. Patients on long term treatment should be monitored closely for appearance of hepatic or pulmonary symptoms and other evidence of toxicity. Discontinue treatment if otherwise unexplained pulmonary, hepatotoxic, haematological or neurological syndromes occur. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, fructose intolerance, or sucrase-isomaltase insufficiency should not take this medicine. **Interactions:** Increased malabsorption with food or agents delaying gastric emptying. Decreased absorption with magnesium trisilicate. Decreased renal excretion by probenecid and sulfinpyrazone. Decreased anti-bacterial activity carbonic anhydrase inhibitors and urine alkalinisation. Anti-bacterial antagonism by quinolone anti-infective. Antibacterial inactivate oral typhoid vaccine. Interference with some tests for glucose in urine. **Pregnancy and lactation:** Should be used at the lowest dose as appropriate for a specific indication, only after careful assessment. Maternal side effects may adversely affect course of pregnancy. Contraindicated in infants under 3 months of age and in pregnant women during labour and delivery. Nitrofurantoin is detected in trace amounts in breast milk. Breast feeding an infant known or suspected to have an erythrocyte enzyme deficiency (including G6PD deficiency) must be temporarily avoided. **Effects on ability to drive and use machines:** May cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected in this way until such symptoms go away. **Undesirable effects:** For full list of side effects, consult SmPC. 'Rare side effect' and 'side effects with unknown frequency' are included in this prescribing information. *Rare side effects ($\geq 1/10,000$ to $< 1/1,000$):* aplastic anaemia, collapse and cyanosis. *Side effects of unknown frequency:* superinfection by fungi or resistant organisms such as *pseudomonas*, agranulocytosis, leukopenia, granulocytopenia, thrombocytopenia, haemolytic anaemia, megaloblastic anaemia, eosinophilia, glucose-6-phosphatedehydrogenase deficiency, anaphylaxis, angioneurotic oedema, cutaneous vasculitis, psychotic reactions, depression, euphoria, confusion, benign intracranial hypertension, peripheral neuropathy including optic neuritis, nystagmus, vertigo, dizziness, headache, drowsiness, pulmonary fibrosis, possible association with lupus-erythematosus-like syndrome, acute pulmonary reactions, subacute pulmonary reactions, chronic pulmonary reactions, cough, dyspnoea, sialoadenitis, pancreatitis, anorexia, emesis, abdominal pain, diarrhoea, nausea, chronic active hepatitis (can be fatal), hepatic necrosis, autoimmune hepatitis, cholestatic jaundice, interstitial nephritis, yellow or brown discolouration of urine, asthenia, fever, chills, arthralgia, drug fever, lupus-like syndrome associated with pulmonary reaction, drug rash with eosinophilia, systemic symptoms (DRESS syndrome), exfoliating dermatitis, erythema multiforme (including Stevens-Johnson syndrome), maculopapular, erythematous or eczematous eruptions, rash, urticaria, purities, transient alopecia. **Legal Category:** Prescription only medicine. **Pack quantities and costs:** £9.50 per pack of 14 capsules. **Marketing Authorisation Holder:** Mercury Pharmaceuticals Ltd, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK. **Marketing Authorisation Number:** PL 12762/0052. **Date of Preparation:** March 2023 [UK/NIT/PM/0011]

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 **Advanz Pharma Medical Information** via telephone on +44 0 8700 70 30 33 or via e-mail at medicalinformation@advanzpharma.com