PRESCRIBING INFORMATION

Macrobid® (Nitrofurantoin MR Capsules)
Macrodantin® (Nitrofurantoin Capsules)

Presentation: Macrobid capsules are supplied as modified release hard gelatin capsules containing 100mg nitrofurantoin in macrocrystalline and monohydrate forms. Macrodantin capsules are supplied as hard gelatin capsules containing 50mg or 100mg nitrofurantoin in macrocrystalline form.

Indications: Treatment and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections (UTI) or pyelitis either spontaneous or following surgical procedures. Nitrofurantoin is specifically indicated for the treatment of infections due to susceptible strains of *Escherichia coli*, *Enterococcus sp*, *Staphylococcus sp*, *Citrobacter sp*, *Klebsiella sp*, and *Enterobacter sp*. Macrobid is not indicated for treatment of associated renal cortical or peri-nephric abscesses.

Dosage and Administration: For oral administration taken with food or milk.

Macrobid capsules
Adults and children over 12 years of age: Acute or recurrent uncomplicated UTI and pyelitis - 100mg twice daily for 7 days. Surgical prophylaxis - 100mg twice daily on the day of the procedure and 3 days thereafter. **Elderly:** unless significant renal impairment exists, dosage as for adults ***(See Warnings and Precautions).*** **Children under 12 years:** Macrobid is not suitable for children under 12 years of age.

Macrodantin capsules
Adults: Acute uncomplicated UTI: 50mg four times daily for 7 days. Prophylaxis: 50mg four times daily for the duration of the procedure, and for 3 days after. In addition Macrodantin can also be used for severe chronic recurrence (UTIs):100mg four times daily for seven days and long term suppression: 50-100 mg once a day. **Elderly:** unless significant renal impairment exists, dosage as for adults (See Warnings and Precautions). **Children and infants over 3 months of age:** Acute urinary tract infections: 3mg/kg/day in four divided doses for seven days. Suppressive - 1mg/kg, once a day. For children less than 25 kg body weight consideration should be given to the use of the suspension.

Contraindications: Known hypersensitivity to Nitrofurantoin or other nitrofurans, or ingredients of Macrobid/Macrodantin capsules. Patients with renal dysfunction, G6PD deficiency, acute prophyria, pregnancy at term (including labour and delivery) and in infants under 3 months of age.

Warnings and Special Precautions: Use with caution in patients with pulmonary (lung) disease, hepatic (liver) dysfunction, neurological disorders, peripheral neuropathy, anaemia, diabetes mellitus, those with vitamin B or folate deficiency, electrolyte imbalance and allergic diathesis. May cause haemolysis in patients with deficiency of glucose-6-phosphate dehydrogenase. Patients on long term treatment should be monitored for appearance of hepatic or pulmonary symptoms and other evidence of toxicity. Taking the drug with food or milk or adjustment of dosage minimises GI reactions. Urine may be coloured yellow or brown, may cause false positive for urinary glucose. Discontinue treatment if otherwise unexplained pulmonary, hepatotoxic, haematological or neurological syndromes occur. Contains lactose.

Pregnancy and Lactation: Contraindicated in pregnancy at term (including labour and delivery). Nitrofurantoin is detected in trace amounts in breast milk. Should be avoided if breast feeding infants suspected to have G6PD deficiency.

Interactions: Concurrent use with quinolones, magnesium trisilicate, uricosuric drugs such as probenecid and sulphinpyrazone, carbonic anhydrase inhibitors, urine alkalinising agents, oestrogen, oestrogen containing contraceptives and oral typhoid vaccine is not recommended. Increased absorption with food or agents delaying gastric emptying.

Adverse Effects: Nausea, anorexia, emesis, abdominal pain and diarrhoea have been reported. Less common and rare are those events that affect the respiratory system. Acute pulmonary reactions occur in first week of treatment and are reversible with cessation of therapy. Sub-acute and chronic reactions (collapse, cyanosis, fever, chills, cough and dyspnoea) can occur with continuous treatment for six months or more. Hepatic (reactions including cholestatic jaundice, and chronic active hepatitis which may lead to hepatic necrosis occur rarely). Fatalities have been reported. Neurological (peripheral neuropathy and optic neuritis infrequently), haematological (anaemias, G6PD deficiency and other rarely reported events such as leucopoenia, agranulocytosis, granulocytopenia and thrombocytopenia resolve with cessation of therapy). Allergic reactions including rashes eczematous eruptions and pruritus. Angioneurotic oedema, anaphylaxis, Lupus-like syndrome, sialadenitis, pancreatitis. Transient alopecia and benign intracranial hypertension have been reported. Superinfections by fungi or pseudomonas may occur.

Please refer to Summary of Product Characteristics for detailed information.

Legal Category: POM.
Basic NHS Price: Macrobid: £5.87 per pack of 14 capsules. Macrodantin: £3.66 per 30-capsules pack of 50mg, £6.91 per 30-capsules pack of 100mg

Marketing Authorisation Number: Macrobid 100mg PL 12762/0052, Macrodantin 50mg PL 12762/0048, Macrodantin 100mg PL 12762/0049

Marketing Authorisation Holder: Mercury Pharma Group, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK
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Adverse events should be reported to the local regulatory authority.
Reporting forms and information can be found at http://yellowcard.mhra.gov.uk
Adverse events should also be reported to **Mercury Pharma Medical Information** at **08700 70 30 33** or via e-mail **to medicalinformation@mercurypharma.com**

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