

PRESCRIBING INFORMATION

Macrobid® 100mg Prolonged-release Capsules (nitrofurantoin)

Presentation: Hard gelatin capsules, containing 100mg modified-release nitrofurantoin in macrocrystalline and monohydrate forms.

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

Dosage and administration: For oral administration. *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. *Children under 12 years:* Not recommended.

Contraindications: Known hypersensitivity to nitrofurantoin or other nitrofurans, or any of the ingredients. In patients with severe renal dysfunction with an eGFR of less than 45 ml/min, G6PD deficiency and acute porphyria. In pregnancy at term (including labour and delivery) and infants under 3 months of age.

Precautions and warnings: Not effective for the treatment of parenchymal infections of unilaterally functioning kidney. Caution is advised in patients with pulmonary disease, mild to moderate renal impairment, hepatic dysfunction, neurological disorders, and allergic diathesis. Severe or irreversible peripheral neuropathy may occur and may be life-threatening. Treatment should be stopped at the first signs of paraesthesiae. Caution in patients with anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions and vitamin B (particularly folate) deficiency. Immediately discontinue or closely monitor if acute, sub-acute or chronic pulmonary reactions (fibrosis and diffuse interstitial pneumonitis especially in the elderly) occur. Closely monitor for signs of hepatitis (particularly during long-term use). May discolour urine and cause false positive urinary glucose test. Discontinue treatment at any sign of haemolysis in those with suspected G6PD deficiency or if any unexplained pulmonary, hepatic, haematological or neurological syndromes occur. Gastrointestinal reactions may be minimised by taking the drug with food or milk, or by adjustment of dosage. Contains lactose.

Pregnancy and lactation: Use at the lowest dose as appropriate only after careful assessment. Contraindicated in pregnancy at term (including labour and delivery). Nitrofurantoin is detected in trace amounts in breast milk.

Interactions: Quinolones, magnesium trisilicate, probenecid, sulphapyrazone, carbonic anhydrase inhibitors, urine alkalinising agents, oestrogens and oral typhoid vaccine.

Undesirable effects: Nausea and anorexia have been reported. Acute pulmonary reactions (minor symptoms such as fever, chills, cough and dyspnoea may be significant) usually occur in first week of treatment and are reversible with cessation of therapy. Chronic pulmonary reactions can occur with continuous treatment for six months or more and are common in elderly patients. Hepatic reactions (including hepatotoxicity), neurological reactions (e.g. peripheral neuropathy) and haematological (e.g. anaemia's, leucopenia, agranulocytosis, granulocytopenia and thrombocytopenia) resolve with cessation of therapy. Cholestatic jaundice and chronic active hepatitis occur rarely. Anaphylaxis, sialadenitis, pancreatitis, drug fever and arthralgia may also occur. Allergic reactions. Transient alopecia and benign intracranial hypertension have been reported.

Overdose: Symptoms and signs of overdose include gastric irritation, nausea and vomiting. There is no specific antidote. Nitrofurantoin can be haemodialysed. Standard treatment is by induction of emesis or by gastric lavage in cases of recent ingestion.

(Please refer to the Summary of Product Characteristics for detailed information)

Legal Category: POM.

Basic NHS Price: £9.50 per pack of 14 capsules.

Marketing authorisation number: PL 12762/0052

Marketing authorisation holder: Concordia International, 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

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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 **Concordia International Medical Information** via telephone on **+44 (0) 8700 70 30 33** or via e-mail at medicalinformation@concordiarx.com

References

1. Data on file Macrobid cost savings April 2017.