# PRESCRIBING INFORMATION

## NITROFURANTOIN

**Nitrofurantoin Tablets BP**

**50 mg and 100 mg**

**Urinary Antibacterial**

**AA PHARMA INC.**
**1165 Creditstone Road, Unit #1**
**Vaughan, Ontario**
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## THERAPEUTIC CLASSIFICATION

Urinary Antibacterial

## INDICATIONS

The treatment of pyelonephritis, pyelitis, and cystitis when due to susceptible organisms. Not indicated for the treatment of associated renal cortical or perinephric absecesses, nor in prostatitis.

## CONTRAINDICATIONS

Anuria, aliguria, or significant impairment of renal function (creatinine clearance under 40 ml/min.) are contraindications to nitrofurantoin carries an increased risk of toxicity because of impaired excretion of the drug. For the same reason, the drug is much less effective under these circumstances.

Nitrofurantoin is contraindicated in pregnant patients at term as well as in infants under 1 month of age, because of the possibility of hemolytic anemia due to immature enzyme systems (glutathione instability).

Known hypersensitivity to nitrofurantoin.

## PRECAUTIONS

Hemolytic anemia of the primaquine-sensitivity type has been induced by nitrofurantoin. The hemolysis appears to be linked to a glucose-6-phosphate dehydrogenase deficiency in the affected patientsô red blood cells. This deficiency is found in 10% of Negroes and in a small percentage of ethnic groups of Mediterranean and Near-Eastern origin. Any sign of hemolysis is an indication to discontinue the drug. Hemolysis ceases when the drug is withdrawn.

Nitrofurantoinôs safety during pregnancy and lactation has not been established. It should not be used in women of childbearing potential unless the expected benefits outweigh the possible hazards.

Predisposing conditions such as renal impairment, anemia, diabetes, electrolyte imbalance, vitamin B deficiency, and debilating disease may enhance the occurrence of peripheral neuropathy. Peripheral neuropathy may occur with nitrofurantoin therapy; this may become severe or irreversible. A fatality has been reported. If numbness or tingling occurs, discontinue the drug.

Do not administer nitrofurantoin concomitantly with drugs which may produce impaired renal function.

## ADVERSE EFFECTS

Gastrointestinal: Anorexia, nausea, emesis are the most frequent reactions; less frequently, abdominal pain and diarrhea: rarely, hepatitis. This dose-related toxicity reaction can be minimized by reduction of dosage, especially in the female patient.

Hypersensitivity: pulmonary sensitivity reactions, which can be acute, subacute, or chronic.

Acute reaction is commonly manifested by fever, chills, cough, chest pain, dyspnea, pulmonary infiltration with consolidation or pleural effusion on X-ray, and eosinophilia. The acute reactions usually occur within the first week of treatment and resolve with cessation of the drug therapy.

Subacute or chronic pulmonary reaction is associated with prolonged therapy. Insidious onset of malaise, dyspnea on exertion, cough, altered pulmonary function, and roentgenographic and histologic findings of diffuse interstitial pneumonitis or fibrosis or both are common manifestations. Impaired pulmonary function may result even after cessation of the drug therapy.

Dermatologic: maculopapular, erythematous, or eczematous eruption, pruritus, urticaria, angioedema.

Other sensitivity reactions: anaphylaxis, asthmatic attack in patients with history of asthma, cholestatic jaundice, drug fever, arthralgia.

Hematologic: hemolytic anemia, granulocytopenia, eosinophilia, magaloblastic anemia. Return of the blood picture to normal has followed cessation of therapy. Neurological: peripheral neuropathy, headache, dizziness, nystagmus, and drowsiness.

Miscellaneous: transient alopecia. As with other antimicrobial agents, superinfections by resistant organism may occur. With nitrofurantoin, however, these are limited to the genitourinary tract because suppression of normal bacterial flora elsewhere in the body does not occur. Pseudomonas is the organism most commonly implicated in superinfections inpatients treated with nitrofurantoin.

## OVERDOSAGE

Symptoms: Occasional incidents of acute overdose of nitrofurantoin have not resulted in any specific symptomatology other than vomiting.

Treatment: In case vomiting does not occur soon after an excessive dose, induction of emesis is recommended. There is no specific antidote for nitrofurantoin but a high fluid intake should be maintained to promote urinary excretion of the drug, but only in case of overdosage.

## DOSAGE

To minimize gastric upset, administer the drug with food or milk. Adults: 50 to 100 mg 4 times a day.

Continue therapy for at least 1 week and for at least 3 days after sterility of the urine is obtained. Continued infection indicates the need for reevaluation.

If the drug is to be used for long-term suppressive therapy, consider a dosage reduction.

## AVAILABILITY OF DOSAGE FORMS

Each scored tablet, contains: nitrofurantoin 50 mg or 100 mg.