NITROFURANTOIN

NITRO
100 mg Capsule
ANTIBACTERIAL

℞

FORMULATION:
Each hard gelatin capsule contains:
Nitrofurantoin USP ..... 100 mg

PRODUCT DESCRIPTION:
Blue/Blue colour hard gelatin capsule containing size "2" yellow colour powder.

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Antibacterials for systemic use, nitrofuran derivatives.

MECHANISM OF ACTION:
Nitrofurantoin interferes with cell metabolism and cell wall synthesis by inhibiting several enzyme systems including acetyl coenzyme A. It is bactericidal to most Gram-positive and Gram-negative urinary tract pathogens.

PHARMACOKINETICS:
Absorption: Readily absorbed from the GI tract. Food may increase bioavailability and prolong the duration of therapeutic urinary concentrations.
Distribution: Concentrations in blood and body tissues are low; crosses the placenta and the blood-brain barrier and distributes in breast milk (trace amounts).
Metabolism: Hepatic and in most body tissues.
Excretion: Via urine (30-40% of a dose excreted rapidly as unchanged drug); some tubular reabsorption may occur in acid urine. Plasma half-life: 0.3-1 hr.

INDICATIONS:
Urinary tract Infections due to susceptible strains of *E. Coli., S. aureus* & certain susceptible strains of *Klebsiella* and *Enterobacter.*

DOSAGE AND ADMINISTRATION:
Adults: 50-100 mg 6 hourly with meals.
Children: 6 mg/kg body weight daily in 4 divided doses.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Hypersensitivity, anuria, oliguria, hepatitis, pregnancy at term (during labor & delivery), infant <1 month.

ADVERSE DRUG REACTIONS:
Nausea, emesis, anorexia, abdominal pain, diarrhea, pulmonary hypersensitivity reaction, peripheral neuropathy, exfoliative dermatitis, erythema multiforme, lupus-like syndrome, urticaria, rash, agranulocytosis, leukopenia, and granulocytopenia.

WARNINGS / PRECAUTIONS:
Elderly. Monitor hepatic and pulmonary function during prolonged therapy. Pre-existing pulmonary, hepatic, neurological, or allergic disorders, predisposition to peripheral neuropathy e.g., renal impairment, anemia, electrolyte imbalance, debility, vitamin B deficiency. Withdraw if signs of peripheral neuropathy occur. Lactation.

PREGNANCY:
Animal studies with Nitrofurantoin have shown no teratogenic effects. Nitrofurantoin has been in extensive clinical use since 1952, and its suitability in human pregnancy has been well documented. However, as with all other drugs, the maternal side effects may adversely affect course of pregnancy. The drug should be used at the lowest dose as appropriate for a specific indication, only after careful assessment.

Nitrofurantoin is however contraindicated in infants under three months of age and in pregnant women during labour and delivery, because of the possible risk of haemolysis of the infants' immature red cells.

LACTATION:
Breast feeding an infant known or suspected to have an erythrocyte enzyme deficiency (including G6PD deficiency) must be temporarily avoided since Nitrofurantoin is detected in trace amounts in breastmilk.

DRUG INTERACTIONS:
Reduced excretion with probenecid or sulfinpyrazone. Absorption reduced by magnesium trisilicate. Antagonistic effects with quinolone antibacterials. Reduced effects with carbonic anhydrase inhibitors or urinary alkalinisers.

OVERDOSE AND TREATMENT:
Symptoms
Symptoms and signs of overdose include gastric irritation, nausea and vomiting.

Management
There is no known specific antidote. However, Nitrofurantoin can be haemodialysed in cases of recent ingestion. Standard treatment is by induction of emesis or by gastric lavage. Monitoring of full blood count, liver function, and pulmonary function tests are recommended. A high fluid intake should be maintained to promote urinary excretion of the drug.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

Keep all medicines out of reach of children.

AVAILABILITY:
Alu/PVC Blister Pack x10's (Box of 20's)

DR-XY44337
Date of First Authorization: March 23, 2015
Date of Revision of Package Insert: December 16, 2020

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Manufactured by:
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