NITROFURANTOIN 100MG TABLETS (Nifuran® -100)

COMPOSITION:
Nifuran® 100 Tablets:
Each tablet contains Nitrofurantoin BP 100mg.

PROPERTIES, ACTIONS AND FATE:
Nifuran® Tablets contain Nitrofurantoin, a nitrofuran antibiotic which is active against many Gram-negative and Gram-positive urinary-tract pathogens.

Nitrofurantoin is bactericidal and its mode of action is uncertain but appears to depend on the formation of reactive intermediates by reduction; this process occurs more efficiently in bacterial than in mammalian cells.

Nitrofurantoin is readily absorbed from the gastrointestinal tract. The absorption rate is dependent on crystal size. The macrocrystalline form has slower dissolution and absorption rates, produces lower serum concentrations than the microcrystalline form, and takes longer to achieve peak concentrations in the urine. The presence of food in the gastrointestinal tract may increase the bioavailability of nitrofurantoin and prolong the duration of therapeutic urinary concentrations. Nitrofurantoin is metabolised in the liver and most body tissues while about 30% to 50% of a dose is excreted rapidly in the urine as unchanged nitrofurantoin, some tubular reabsorption may occur in acid urine.

INDICATIONS:
Nifuran® Tablets are indicated in the treatment and prophylaxis of uncomplicated lower urinary-tract infections caused by or associated with pathogens sensitive to nitrofurantoin therapy. It is also used as a long-term prophylactic therapy in recurrent infections.

DOSAGE AND ADMINISTRATION:
Nifuran® Tablets are administered by the oral route at the usual dosage of 50 to 100mg four times daily, with food or milk, in order to reduce the gastrointestinal disturbances. In uncomplicated infection 50mg three times daily, or 100mg twice daily, may be adequate. Treatment is usually continued for up to 14 days. A usual prophylactic dose is 50 to 100mg at bedtime. Infants over 1 month of age and older children may be given 3 to 7mg per kg body-weight daily in 4 divided doses by mouth.

For long-term prophylactic therapy 1mg per kg body-weight daily may be adequate.

PRECAUTIONS AND WARNINGS:
1. **Nifuran®** Tablets should not be given to patients with impaired renal function since antibacterial concentrations in the urine may not be attained and toxic concentrations in the plasma can occur.

   Nitrofurantoin is also contraindicated in patients known to be hypersensitive, in those with a deficiency of glucose-6-phosphate dehydrogenase, and in infants less than one month old.
2. It is recommended that nitrofurantoin should not be used in pregnant patients at term because of the possibility of producing haemolytic anaemia in the neonate, and that it should be avoided or used with caution in nursing mothers of infants with a deficiency of glucose-6-phosphate dehydrogenase since traces are found in the milk.
3. **Nifuran®** Tablets should be used with caution in the elderly and in patients with pre-existing pulmonary, hepatic, neurological or allergic disorders, and in those with conditions such as anaemia, diabetes mellitus and electrolyte imbalance which may predispose to peripheral neuropathy. The medication should be discontinued if signs of peripheral neuropathy develop.
4. Antagonism between nitrofurantoin and nalidixic acid and nitrofurantoin and oxolinic acid has been demonstrated, thus nitrofurantoin should not be given concomitantly with quinolones. Probenocid or sulphinpyrazone may reduce the excretion of nitrofurantoin and should not be given concomitantly.

ADVERSE EFFECTS:
The most frequent adverse effects of nitrofurantoin are gastrointestinal disturbances. They are dose-related and generally include nausea, vomiting, and anorexia; abdominal pain and diarrhoea occur less frequently. Neurological adverse effects include headache, drowsiness, vertigo, dizziness, nystagmus, intracranial hypertension and peripheral polyneuropathy.

Hypersensitivity reactions such as skin rashes, urticaria, pruritus, fever, and angioedema may occur. Acute pulmonary sensitivity reactions characterised by sudden onset of fever, chills, eosinophilia, cough, chest pain, dyspnoea, pulmonary infiltration or consolidation, and pleural effusion may occur within hours to a few days of beginning therapy, but they usually resolve on discontinuation.

LEGAL CATEGORY: Prescription only medicine (POM).

THERAPEUTIC CATEGORY: ATC: JO1K (other systemic antibiotics)

STORAGE: Store in a dry place below 30°C. Protect from light. Keep out of reach of children. Protect the tablets from exposure to air and moisture. Protect from crushing and mechanical shock.

SHELF LIFE: As per the product label.

PRESENTATION: Nifuran® Tablets in packs of 100's and 1000's tablets.

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