Nintoin®

Nitrofurantoin

Presentation
Nintoin® Tablet: Each tablet contains Nitrofurantoin USP 100 mg.
Nintoin® 50 Capsule: Each capsule contains Nitrofurantoin USP 50 mg.
Nintoin® SR Capsule: Each capsule contains Nitrofurantoin USP 100 mg.
Nintoin® Suspension: Each 5 ml suspension contains Nitrofurantoin USP 25 mg.

Description
Nitrofurantoin is an antibacterial agent specific for urinary tract infections. Nitrofurantoin is highly soluble in urine, to which it may impart a brown color. Nitrofurantoin inactivates or alters bacterial ribosomal proteins and other macromolecules. Nitrofurantoin has been shown to be active against the following bacteria: Gram-Positive Aerobes- *Staphylococcus saprophyticus, Coagulase-negative staphylococci (including Staphylococcus epidermidis), Enterococcus faecalis, Staphylococcus aureus, Streptococcus agalactiae, Group D streptococci, Viridans group streptococci*. Gram-Negative Aerobes- *Escherichia coli, Citrobacter amalonaticus, Citrobacter diversus, Citrobacter freundii, Klebsiella oxytoca, Klebsiella ozaenae*.

Indications and Uses
Nitrofurantoin is specifically indicated for the treatment & prophylaxis of urinary tract infections caused by susceptible strains of *Escherichia coli, Enterococci, Staphylococcus aureus, Staphylococcus saprophyticus* and certain susceptible strains of *Klebsiella* and *Enterobacter* species.

Dosage and Administration
Nitrofurantoin tablet
Nitrofurantoin tablet should be taken with food.

Adults: 50-100 mg four times a day - the lower dosage level is recommended for uncomplicated urinary tract infections.

Therapy should be continued for one week or for at least 3 days after sterility of the urine is obtained.

For long-term suppressive therapy in adults, a reduction of dosage to 50-100 mg at bedtime may be adequate.

Nitrofurantoin capsule
Nitrofurantoin capsule should be taken with food.

Adults:
Acute Uncomplicated Urinary Tract Infections (UTIs): 50 mg four times daily for 7 days.
Long term suppression: 50-100 mg once a day.
Prophylaxis: 50 mg four times daily for the duration of procedure and for three days thereafter.

Nitrofurantoin SR capsule
Nitrofurantoin capsule should be taken with food.

Adults and Children over 12 years: One 100 mg capsule every 12 hours for seven days.
Genito-urinary surgical prophylaxis: One capsule twice daily on day of procedure and for next 3 days.

Nitrofurantoin suspension
Children: 5-7 mg/kg/day in four divided doses (contraindicated under one month of age).
The average dose of Nintoin suspension for pediatric patients can be calculated from the following table:

Body weight (kg)	No. of Teaspoonfuls (4 times daily)
7 to 11	½ (2.5 ml)
12 to 21	1 (5 ml)
22 to 30	1½ (7.5 ml)
31 to 41	2 (10 ml)

Therapy should be continued for one week or for at least 3 days after sterility of the urine is obtained.

For long-term suppressive therapy in children, doses as low as 1 mg/kg per 24 hours, given in a single dose or in two divided doses, may be adequate.

Contraindications
Anuria, oliguria or significant impairment of renal function are contraindications. This drug is contraindicated in pregnant patients at 38-42 weeks, during labor and delivery. Nitrofurantoin is also contraindicated in those patients with known hypersensitivity to Nitrofurantoin.

Precautions
If acute, sub-acute or chronic pulmonary reactions occur, Nitrofurantoin should be discontinued. Antacid preparations containing magnesium trisilicate should not be taken while taking Nitrofurantoin.

Side-effects
The most frequent clinical adverse events are nausea, headache, and flatulence. Other less occurred adverse events are diarrhea, dyspepsia, abdominal pain, constipation, emesis, dizziness and drowsiness.

Use in pregnancy & lactation
Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.
Nitrofurantoin has been detected in human breast milk in trace amounts. Because of the potential for serious adverse reactions from Nitrofurantoin in nursing infants under one month of age, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Drug interactions
Antacids containing Magnesium Trisilicate, when administered concomitantly with Nitrofurantoin, reduce both the rate and extent of absorption of Uricosuric drugs, such as Probenecid and Sulfinpyrazone, can inhibit renal tubular secretion of Nitrofurantoin.

Overdosage
Occasional incidents of acute overdosage of Nitrofurantoin have not resulted in any specific symptoms other than vomiting. Induction of emesis is recommended.

Storage
Do not store above 30^0 C. Keep away from light and out of the reach of children.

Commercial Pack
Nintoin® Tablet: Each box contains 3 blister strips of 10 tablets.
Nintoin® 50 Capsule: Each box contains 3 blister strips of 10 capsules.
Nintoin® SR Capsule: Each box contains 2 blister strips of 10 capsules.
Nintoin® Suspension: Each bottle contains 100 ml suspension.

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