Only for the use of Medical Professionals

Nitrofur®

Nitrofurantoin

Description

Nitrofur® is a preparation of Nitrofurantoin which 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

Nitrofur® is specifically indicated for the treatment and prophylaxis of urinary tract infections when due to susceptible strains of *Escherichia coli, Enterococci, Staphylococcus aureus, Staphylococcus saprophyticus* and certain susceptible strains of *Klebsiella* and *Enterobacter* species.

Dosage and administration

Nitrofur® SR capsule

Adults and children over 12 years: 100 mg capsule twice daily for seven days.

Genito-urinary surgical prophylaxis: 100 mg capsule twice daily on the day of the procedure and for next 3 days.

Prophylaxis of urinary tract infection: 50 to 100 mg once daily.

Nitrofur® suspension

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

Children (1 month or older): 5-7 mg/kg of body weight per 24 hours, given in four divided doses (contraindicated under one month of age). The average dose of **Nitrofur® suspension** for children can be calculated as follows:

Dosing table for children	
Weight in kg	**Doses and frequency**
7 kg to 11 kg	2.5 ml (½ teaspoonful) four times daily
12 kg to 21 kg	5 ml (1 teaspoonful) four times daily
22 kg to 30 kg	7.5 ml (1 ½ teaspoonfuls) four times daily
31 kg to 41 kg	10 ml (2 teaspoonfuls) four times daily
42 kg or greater	As like adult dose

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.

Use in pregnancy and lactation

Pregnancy: Nitrofurantoin is 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.

Lactation: 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.

Side effects

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

Contraindications

Nitrofurantoin is contraindicated in those patients with known hypersensitivity to nitrofurantoin or any of its component. It is also contraindicated in anuria, oliguria, or significant impairment of renal function. This drug is contraindicated in pregnant patients at 38-42 weeks, during labor and delivery.

Warnings and precautions

If acute, sub-acute, or chronic pulmonary reactions occur, nitrofurantoin should be discontinued. Patients should be advised to take nitrofurantoin with food to further enhance tolerance and improve drug absorption.

Drug interactions

Antacids containing magnesium trisilicate, when administered concomitantly with nitrofurantoin, reduce both the rate and extent of absorption. The mechanism for this interaction probably is adsorption of nitrofurantoin onto the surface of magnesium trisilicate. Uricosuric drugs, such as probenecid and sulfinpyrazone, can inhibit renal tubular secretion of nitrofurantoin. The resulting increase in nitrofurantoin serum levels may increase toxicity, and the decreased urinary levels could lessen its efficacy as a urinary tract antibacterial.

Overdose

Occasional incidents of acute overdosage of nitrofurantoin have not resulted in any specific symptoms other than vomiting. Induction of emesis is recommended. There is no specific antidote, but a high fluid intake should be maintained to promote urinary excretion of the drug. Nitrofurantoin is dialyzable.

Pharmaceutical precautions

Nitrofur® SR capsule: Store in a cool (below 25°C) and dry place protected from light.

Nitrofur® suspension: Store in a cool and dry place protected from light.

Presentation

Nitrofur® SR 50 capsule: Each sustained release capsule contains Nitrofurantoin USP 50 mg.

Nitrofur® SR 100 capsule: Each sustained release capsule contains Nitrofurantoin USP 100 mg.

Nitrofur® suspension: Each 5 ml suspension contains Nitrofurantoin BP 25 mg.

Package quantities

Nitrofur® SR 50 capsule: Carton of 30 capsules in blister pack.

Nitrofur® SR 100 capsule: Carton of 30 capsules in blister pack.

Nitrofur® suspension: Bottle of 100 ml.

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ACI Limited
Godnyl, Narayanganj, Bangladesh