

Uritro[®]

Nitrofurantoin

COMPOSITION:

Uritro[®] SR 50 Capsule: Each sustained release capsule contains Nitrofurantoin Monohydrate equivalent to Nitrofurantoin USP 50 mg.

Uritro[®] SR 100 Capsule: Each sustained release capsule contains Nitrofurantoin Monohydrate equivalent to Nitrofurantoin USP 100 mg.

Uritro[®] Suspension : Each 5 ml suspension contains Nitrofurantoin USP 25 mg.

PHARMACOLOGY:

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*.

INDICATION:

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*, *Citrobacter* and *Enterobacter species*.

DOSE & ADMINISTRATION:

Uritro[®] SR Capsule

Adults: **Acute Uncomplicated Urinary Tract Infections (UTIs):** 100 mg twice daily for 7 days or 50 mg four times daily for 7 days.

Long term suppression: 50-100 mg once a day.

Genito – Urinary surgical Prophylaxis: 100 mg twice daily on the day of procedure and for 3 days after.

Surgical Prophylaxis: 100 mg twice daily on the day of procedure and for 3 days thereafter or 50 mg four times daily for the duration of procedure and for 3 days thereafter.

Children: 5-7 mg/kg/day in four divided doses.

The average dose of Uritro[®] oral suspension for pediatric patients can be calculated from the following table:

Body Weight (KG)	No of Teaspoonfuls (4 times daily)
7 to 11	1/2 (2.5 ml)
12 to 21	1 (5 ml)
22 to 30	1 1/2 (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.

Uritro[®] SR capsule should be taken with food.

CONTRA-INDICATION:

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.

WARNING AND PRECAUTION:

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.

USE IN CHILDREN & ADOLESCENTS:

Nitrofurantoin is contraindicated for children under one month of age.

DRUG INTERACTION:

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.

OVERDOSE:

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

STORAGE:

Store in a dry and cool place below 30^o C temperature and keep away from light and moisture. keep out of reach of children.

PACKING:

Uritro[®] SR 50 Capsule: Each box contains of 3 X 10's capsules in Alu-PVC blister strips.

Uritro[®] SR 100 Capsule: Each box contains of 2 X 10's capsules in Alu-PVC blister strips.

Uritro[®] Suspension: Each bottle contains 100 ml suspension with a 10 ml measuring cup.



Manufactured by

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