Utifin SR

Nitrofurantoin USP

COMPOSITION

Utifin SR Capsule: Each capsule contains Nitrofurantoin USP 100 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 inhibit bacterial enzymes involved in the synthesis of DNA, RNA, cell wall protein synthesis, and other metabolic enzymes. Nitrofurantoin has been shown to be active against the following bacteria: Gram-Positive Aerobas- *Staphylococcus saprophyticus*, Coagulasa-negative staphylococci (including *Staphylococcus epidermidis*), *Enterococcus faecalis*, *Staphylococcus auraus*, *Streptococcus agalactiae*, Group D streptococci, Viridans group straptococci. Gram-Negative Aerobes- *Escherichia coli*, *Citrobacter amalonaticus*, *Citrobacter diversus*, *Citrobacter freundii*, *Klebsiella oxytoca*, *Klebsiella ozaenae*.

INDICATIONS

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 & ADMINISTRATION

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 100 mg capsule twice daily on day of procedure and for next 3 days.

CONTRAINDICATIONS

Anuria, oliguria or significant impairment of renal function (creatinine clearance under 60 ml/minute) are contraindications. Because of the possibility of hemolytic anemia due to immature erythrocyte enzyme systems (glutathione instability) the 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 & 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 SPECIAL POPULATION

Pregnancy: Safe in pregnancy. There are no adequate and wall-controlled studies in pregnant woman. 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.

Use in the elderly: The greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy in elderly patients should be considered when prescribing Nitrofurantoin.

Use in pediatric population: Nitrofurantoin is contraindicated in infants below the age of one month. Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

DRUG INTERACTION

Antacids containing magnesium trisilicate, when administered concomitantly with Nitrofurantoin, reduce both the rate and extent of absorption. 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. There is no specific antidote, but a high fluid intake should be maintained to promote urinary excretion of the drug.

STORAGE

- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING

Utifin SR Capsule: Each box contains 20 Capsule in alu-alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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