

For the use only of a Registered
Medical Practitioner or a Hospital or a Laboratory

8020737-9093

HERNFT-SR

(Nitrofurantoin SR Tablets)

Composition

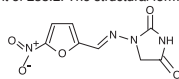
Each uncoated sustained release tablet contains :

Nitrofurantoin I.P. 100 mg

Excipients q.s

Pharmacological Properties

The chemical name of HERNFT-SR is 1-(5-nitrofururylideneamino)imidazolidine-2,4-dione. Its molecular formula is $C_6H_8N_4O_5$ and has a molecular weight of 238.2. The structural formula is :



Dosage and Method of Administration

The normal adult dose of HERNFT-SR is 100 mg twice daily. The pediatric dose is 3 mg/kg/day in four divided doses. HERNFT-SR should be taken with food, as this improves the absorption of the drug by 45%. The tablet should be swallowed and not chewed, cut or crushed from its original form.

Uses

HERNFT-SR is only clinically proven for use against *E. coli* or Staph. saprophyticus. It may also have *in vitro* activity against : Coagulase-negative *staphylococci*, *Enterococcus faecalis*, *Staphylococcus aureus*, *Streptococcus agalactiae*, *Citrobacter species*, *Klebsiella species*, and is used in the treatment of infections caused by these organisms.

Contraindications

Hypersensitivity to any components of this product.

Adverse Effect

HERNFT-SR cause nausea and vomiting, fever, rash. It can also cause pulmonary fibrosis. All these side effects are much more common in the elderly. Patients should be informed that nitrofurantoin colours urine a dark orange-brown; this is completely harmless. Neonates (babies up to the age of one month) have

immature enzyme systems in their red blood cells (glutathione instability) and nitrofurantoin must therefore not be used because it can cause haemolytic anaemia. For the same reason, nitrofurantoin should not be given to pregnant women after 38 weeks of pregnancy, or who are about to give birth. HERNFT-SR is contraindicated in patients with decreased renal function due to systemic accumulation and subtherapeutic levels reached in the urinary tract.

Precautions

HERNFT-SR must be taken with food and can cause bleeding in the stomach, vomiting and other gastrointestinal disruptions if these warnings are not adhered to. HERNFT-SR is contraindicated in patients with glucose-6-phosphate dehydrogenase deficiency because of risk of extravascular hemolysis resulting in anemia.

Pharmacokinetic data

Upon Administration HERNFT-SR is metabolized 75% by the liver with the administrated dosage of 100mg and the half life of the drug is 20 minutes. The excretion is urine and bile.

Therapeutic considerations :

Pregnancy category : B(USA) B1(Australia) Gr2(Germany)

Legal Status: Rx

Route of administration: Oral

Self Life: See on the pack

Storage

Store below 25°C, Protect from light and moisture.

Keep out of the reach of children.

Presentation

HERNFT-SR is available as blister strip of 10 tablets.



Marketed by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

Manufactured by :
CORONET LABS PVT. LTD.
Nanhera Anantpur, Puhana- Iqbalpur Road,
Roorkee, Distt. Haridwar (Uttarakhand)