

## **Prescribing information (Summary of Product Characteristics).**

### **1. NAME OF THE MEDICINAL PRODUCT**

Nifuran Tablets.

#### **1.1 Strength:**

Nitrofurantoin 100mg.

#### **1.2 Pharmaceutical Form:**

Tablets.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Each tablet contains:** Nitrofurantoin BP 100mg.

*Full list of excipients provided in section 6.1*

### **3. PHARMACEUTICAL FORM**

Tablets.

Yellow, circular, biconvex tablets, scored on one side and plain on reverse. Packed in blisters of 10 x 10's and contained in a unit box and 1000's HDPE container with literature insert.

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications:**

Nifuran Tablets are indicated in the treatment and prophylaxis of uncomplicated lower urinary-tract infections caused by or associated with pathogens sensitive to nitrofurantoin therapy. It is also used as a long-term prophylactic therapy in recurrent infections.

#### **4.2 Posology and method of administration:**

Nifuran Tablets are administered by the oral route at the usual dosage of 50 to 100mg four times daily, with food or milk, in order to reduce the gastrointestinal disturbances.

In uncomplicated infection 50mg three times daily, or 100mg twice daily, may be adequate.

Treatment is usually continued for up to 14 days. A usual prophylactic dose is 50 to 100mg at bedtime. Infants over 1 month of age and older children may be given 3 to 7mg per kg body-weight daily in 4 divided doses by mouth. For long-term prophylactic therapy 1mg per kg body-weight daily may be adequate.

#### **4.3 Method of administration:**

Nifuran Tablets are administered orally.

#### **4.4 Contraindications**

Patients with known hypersensitivity to nitrofurantoin or other nitrofurans.

Patients suffering from renal dysfunction with creatinine clearance of less than 60ml/minute or elevated serum creatinine G6PD deficiency.

#### **Acute porphyria.**

In infants under three months of age as well as pregnant patients at term (during labour and delivery) because of the theoretical possibility of haemolytic anaemia in the foetus or in the newborn infant due to immature erythrocyte enzyme systems.

#### **4.5 Special Warnings and Precautions for Use:**

1. Nifuran Tablets should not be given to patients with impaired renal function since antibacterial concentrations in the urine may not be attained and toxic concentrations in the plasma can occur. Nitrofurantoin is also contraindicated in patients known to be hypersensitive, in those with a deficiency of glucose-6-phosphate dehydrogenase, and in infants less than one month old.

2. It is recommended that nitrofurantoin should not be used in pregnant patients at term because of the possibility of producing haemolytic anaemia in the neonate, and that it should be avoided or used with caution in nursing mothers of infants with a deficiency of glucose-6-phosphate dehydrogenase since traces are found in the milk.

3. Nifuran Tablets should be used with caution in the elderly and in patients with pre-existing pulmonary, hepatic, neurological or allergic disorders, and in those with conditions such as anaemia, diabetes mellitus and electrolyte imbalance which may predispose to peripheral neuropathy. The medication should be discontinued if signs of peripheral neuropathy develop.

4. Antagonism between nitrofurantoin and Nalidixic acid and nitrofurantoin and oxolinic acid has been demonstrated, thus

nitrofurantoin should not be given concomitantly with quinolones. Probenecid or sulphapyrazone may reduce the excretion of nitrofurantoin and should not be given concomitantly.

#### **4.6 Paediatric population:**

Children and infants over three months of age

Acute urinary Tract infections 3mg/kg/day in four divided doses for seven days.

Suppressive therapy 1mg/kg/once a day.

#### **4.7 Interaction with other medicinal products and other forms of interaction:**

1. Increased absorption with food or agents delaying gastric emptying.

2. Decreased absorption with magnesium trisilicate.

3. Decreased renal excretion of Nitrofurantoin by probenecid and sulphapyrazone.

4. Decreased anti-bacterial activity by carbonic anhydrase inhibitors and urine alkalinisation.

5. Anti-bacterial antagonism by quinolone anti-infectives.

6. Interference with some tests for glucose in urine.

7. As Nitrofurantoin belongs to the group of Antibacterials, it will have the following resulting interactions:

- Oestrogens: In common with other antibiotics, nitrofurantoin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of oestrogen-containing contraceptive products. Therefore, patients should be warned appropriately and extra contraceptive precautions taken.

- Typhoid Vaccine (oral): Antibacterials inactivate oral typhoid vaccine.

#### **4.8 Additional information on special populations:**

No information on this section has been provided.

#### **4.9 Paediatric Population:**

Children and infants over three months of age

Acute urinary Tract infections 3mg/kg/day in four divided doses for seven days.

Suppressive therapy 1mg/kg/once a day.

#### **4.10 Fertility, pregnancy and lactation:**

Animal studies with nitrofurantoin have shown no teratogenic effects. Nitrofurantoin has been in extensive clinical use since 1952 and its suitability in human pregnancy has been well documented. However as with all drugs, the maternal side effects may adversely affect the course of pregnancy. The drug should be used at the lowest dose appropriate for the specific indication, only after careful assessment.

Nitrofurantoin is however contraindicated in infants under three months of age and in pregnant women during labour and delivery, because of the possible risk of haemolysis of the infants' immature red cells. Breast feeding an infant known or suspected to have an erythrocyte enzyme deficiency (including G6PD deficiency), must be temporarily avoided, since Nitrofurantoin is detected in trace amounts in breast milk.

#### **4.11 Effects on ability to drive and use machines:**

Nitrofurantoin may cause dizziness and drowsiness and the patient should not drive or operate machinery if affected this way.

#### **4.12 Undesirable effects:**

The most frequent adverse effects of nitrofurantoin are gastrointestinal disturbances. They are dose-related and generally include nausea, vomiting, and anorexia; abdominal pain and diarrhea occur less frequently. Neurological adverse effects include headache, drowsiness, vertigo, dizziness, nystagmus, intracranial hypertension and peripheral polyneuropathy.

Hypersensitivity reactions such as skin rashes, urticaria, pruritus, fever, and angioedema may occur. Acute pulmonary sensitivity reactions characterized by sudden onset of fever, chills, eosinophilia, cough, chest pain, dyspnoea, pulmonary infiltration or consolidation, and pleural effusion may occur within hours to a few days of beginning therapy, but they usually resolve on discontinuation.

#### **4.13 Overdose:**

Symptoms and signs of overdosage include gastric irritation, nausea and vomiting.

There is no known specific antidote. Nitrofurantoin can be haemodialysed. Standard treatment is by induction of emesis or by gastric lavage in cases of recent ingestion.

Monitoring of full blood count, liver function tests and pulmonary function, are recommended. A high fluid intake should be maintained to promote urinary excretion of the drug.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties:**

**Pharmacotherapeutic Group:** Antiinfectives for Systemic Use, Antibacterials for Systemic Use, Other Antibacterials, Nitrofurantoin derivatives.

**ATC Code:** J01XE01.

Nifuran Tablets contain Nitrofurantoin, a nitrofurantoin antibiotic which is active against many Gram-negative and Gram-positive urinary-tract pathogens.

Nitrofurantoin is bactericidal and its mode of action is uncertain but appears to depend on the formation of reactive intermediates by reduction; this process occurs more efficiently in bacterial than in mammalian cells. Nitrofurantoin is readily absorbed from the gastrointestinal tract. The absorption rate is dependent on crystal size. The microcrystalline form has slower dissolution and absorption rates, produces lower serum concentrations than the microcrystalline form, and takes longer to achieve peak concentrations in the urine.

The presence of food in the gastrointestinal tract may increase the bioavailability of nitrofurantoin and prolong the duration of therapeutic urinary concentrations. Nitrofurantoin is metabolized in the liver and most body tissues while about 30% to 50% of a dose is excreted rapidly in the urine as unchanged nitrofurantoin, some-tubular-reabsorption may-occur in acid urine.

### **5.2 Pharmacokinetic properties:**

Orally administered Nitrofurantoin is readily absorbed in the upper gastrointestinal tract and is rapidly excreted in the urine. Blood concentrations at therapeutic dosages are usually low with an elimination half-life of about 30 minutes.

Maximum urinary excretion usually occurs 2-4 hours after administration of Nitrofurantoin. Urinary drug dose recoveries of about 40-45% are obtained.

### **5.3 Preclinical safety data:**

Carcinogenic effect of Nitrofurantoin in animal studies was observed. However, human data and extensive use of Nitrofurantoin over 50 years do not support such suggestion.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients:**

- White Corn Starch
- Lactose Monohydrate
- Sodium Lauryl Sulphate
- Purified Water
- Magnesium Stearate
- Sodium Starch Glycolate
- Crospovidone

### **6.2 Incompatibilities:**

None Known.

### **6.3 Shelf life:**

36 Months.

### **6.4 Special precautions for storage:**

Store in a dry place, below 30°C.

Protect from light.

Keep all medicines out of reach of children.

### **6.5 Nature and contents of container**

Yellow, circular, biconvex tablets, scored on one side and plain on reverse. Packed in blisters of 10 x 10's and contained in a unit box and 1000's HDPE container with literature insert.

### **6.6 Special precautions for disposal**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES**

### **Marketing Authorization Holder:**

**Company Name:** LABORATORY & ALLIED LTD.

**Address:** Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

**Country:** Kenya

**Telephone:** +254 20 8040306

**Telefax:** +254 20 8040309

**E-Mail:** info@laballied.com

### **Manufacturing Site Address:**

**Company Name:** LABORATORY & ALLIED LTD.

**Address:** Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road, P.O. Box 42875 GPO 00100, Nairobi-Kenya.

**Country:** Kenya

**Telephone:** +254 20 8040306

**Telefax:** +254 20 8040309

**E-Mail:** info@laballied.com

## **8. MARKETING AUTHORIZATION NUMBER:**

**Kenya Reg No.:** H2014/CTD1304/035.

## **9. DATE OF FIRST REGISTRATION/ RENEWAL OF THE REGISTRATION:**

**Registration Date:** 06/02/2014.

**Renewal Date:** To be retained annually.

## **10. DATE OF REVISION OF THE TEXT:**

May, 2024.

## **11. DOSIMETRY (IF APPLICABLE)**

Not Applicable.

## **12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)**

Not Applicable.