

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Furadantin 25mg/5ml Oral Suspension OR Nitrofurantoin 25mg/5ml Oral Suspension

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

Each 5 mL contains 25 mg of nitrofurantoin monohydrate

Excipient(s) with known effect

5mg Methyl parahydroxybenzoate Ph. Eur.per 5ml

1mg Propyl parahydroxybenzoate Ph. Eur.per 5ml

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

An opaque yellow liquid with a lemon/apricot characteristic odour.

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic indications**

For the treatment of and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections or pyelitis either spontaneous or following surgical procedures. It is indicated in adults and children over 3 months of age.

Nitrofurantoin is specifically indicated for the treatment of infections when due to susceptible strains of *Escherichia coli*, *Enterococci*, *Staphylococci*, *Citrobacter*, *Klebsiella* and *Enterobacter*.

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

## Posology

### *Adults*

Acute Uncomplicated Urinary Tract Infections: 50mg four times daily for seven days

Severe Chronic Recurrence: 100mg four times a day for seven days

Long Term Suppression: 50mg - 100mg once a day.

Prophylaxis: 50mg four times daily for the duration of procedure and 3 days thereafter.

### *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: 1mg/kg, once a day.

### *Elderly*

Provided there is no significant renal impairment, in which Nitrofurantoin is contraindicated, the dosage should be that for any normal adult. See precaution and risks to elderly patients associated with long term therapy (see section 4.8).

### *Renal impairment*

Nitrofurantoin is contraindicated in patients with renal dysfunction and in patients with an eGFR of less than 45 ml/minute (see sections 4.3 & 4.4).

## Method of administration

For oral use

This medicine should always be taken with food or milk. Taking Furadantin Oral Suspension/Nitrofurantoin Oral Suspension with a meal improves absorption and is important for optimal efficacy.

## **4.3 Contraindications**

- Hypersensitivity to the active substance, other nitrofurans or to any of the excipients listed in section 6.1.

- Patients suffering from renal dysfunction with an eGFR below 45 ml/minute.
- G6PD deficiency (see also section 4.6).
- 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.

#### **4.4 Special warnings and precautions for use**

Nitrofurantoin is not effective for the treatment of parenchymal infections of unilaterally non-functioning kidney. A surgical cause for infection should be excluded in recurrent or severe cases.

Nitrofurantoin may be used with caution as short-course therapy only for the treatment of uncomplicated lower urinary tract infection in individual cases with an eGFR between 30-44 ml/min to treat resistant pathogens, when the benefits are expected to outweigh the risks.

Since pre-existing conditions may mask adverse reactions, Nitrofurantoin should be used with caution in patients with pulmonary disease, hepatic dysfunction, neurological disorders, and allergic diathesis.

Peripheral neuropathy and susceptibility to peripheral neuropathy, which may become severe or irreversible, has occurred and may be life threatening. Therefore, treatment should be stopped at the first signs of neural involvement (paranesthesia).

Nitrofurantoin should be used with caution in patients with anaemia, diabetes mellitus, electrolyte imbalance, debilitating conditions and Vitamin B (particularly folate) deficiency.

##### **Pulmonary adverse reactions**

Acute, subacute and chronic pulmonary reactions have been observed in patients treated with nitrofurantoin. If these reactions occur, nitrofurantoin should be discontinued immediately. Signs of pulmonary damage include difficulty and or pain when breathing, shortness of breath and coughing up blood or mucus.

##### **Chronic pulmonary reactions**

Chronic pulmonary reactions (including pulmonary fibrosis and diffuse interstitial pneumonitis) can develop insidiously and can often occur in elderly patients.

Close monitoring of the lung disease of patients receiving long-term therapy is indicated (especially in the elderly).

#### Acute pulmonary reactions

Pulmonary reactions may be acute and usually occur within the first week of treatment. Increased vigilance for respiratory symptoms in patients who have just started therapy is warranted (especially in the elderly).

Patients should be monitored closely for signs of hepatitis (particularly in long terms use).

Urine may be coloured yellow or brown after taking Nitrofurantoin. Patients on Nitrofurantoin are susceptible to false positive urinary glucose (if tested for reducing substances).

Nitrofurantoin should be discontinued at any sign of haemolysis in those with suspected glucose-6-phosphate dehydrogenase deficiency.

#### Hepatotoxicity

Hepatic reactions, including hepatitis, autoimmune hepatitis, cholestatic jaundice, chronic active hepatitis, and hepatic necrosis, occur rarely. Fatalities have been reported. The onset of chronic active hepatitis may be insidious, and patients should be monitored periodically for changes in biochemical tests that would indicate liver injury. If hepatitis occurs, the drug should be withdrawn immediately and appropriate measures should be taken.

Discontinue treatment with Nitrofurantoin if otherwise unexplained pulmonary, hepatic, haematological or neurological syndromes occur.

#### Excipient warnings:

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

## **4.5 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 sulfinpyrazone.
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:

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

#### **4.6. Fertility, pregnancy and Lactation**

##### Pregnancy

Animal studies with Nitrofurantoin have shown no teratogenic effects, however study in rats has shown reproductive toxicity (see section 5.3). Nitrofurantoin has been in extensive clinical use since 1952 and its suitability in human pregnancy has been well documented. However, as with all other drugs, the maternal side effects may adversely affect course of pregnancy. The drug should be used at the lowest dose as appropriate for 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

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.

##### Fertility

No data available

#### **4.7 Effects on ability to drive and use machines**

Nitrofurantoin may cause dizziness and drowsiness. Patients should be advised not to drive or operate machinery if affected in this way until such symptoms go away.

#### **4.8 Undesirable effects**

A tabulated list of undesirable effects is outlined below:

The undesirable effects are listed according to organ systems and following frequencies:

Rare ( $\geq 1/10,000$  to  $< 1/1,000$ )

Not known (cannot be estimated from the available data)

System organ class	Frequency	Adverse reaction
Infections and infestations	Not known	Superinfections by fungi or resistant organisms such as Pseudomonas. However, these are limited to the genitourinary tract
Blood and lymphatic system disorders	Rare Not known	Aplastic anaemia  Agranulocytosis, leucopenia, granulocytopenia, haemolytic anaemia, thrombocytopenia, glucose-6-phosphatedehydrogenase deficiency anaemia, megaloblastic anaemia and eosinophilia
Immune system disorders	Not known	Anaphylaxis, angioneurotic oedema, cutaneous vasculitis and allergic skin reactions
Psychiatric disorders	Not known	Psychotic reactions, depression, euphoria, confusion,
Nervous system disorders	Not known	Benign intracranial hypertension, peripheral neuropathy including optic neuritis (sensory as well as motor involvement), nystagmus, vertigo, dizziness, headache and drowsiness.
Cardiac disorders	Rare	Collapse and cyanosis
Respiratory, thoracic and mediastinal disorders	Not known	Pulmonary fibrosis; possible association with lupus-erythematous-like syndrome, acute pulmonary reactions*, subacute pulmonary reactions*, chronic pulmonary reactions*, cough, dyspnoea,

Gastrointestinal disorders	Not known	Sialoadenitis, pancreatitis, anorexia, emesis, abdominal pain, diarrhea and nausea
Hepatobiliary disorders	Not known	Chronic active hepatitis**, hepatic necrosis, autoimmune hepatitis, cholestatic jaundice
Skin and subcutaneous tissue disorders	Not known	Lupus-like syndrome associated with pulmonary reaction. Drug Rash with Eosinophilia and Systemic Symptoms (DRESS syndrome), cutaneous vasculitis, exfoliative dermatitis and erythema multiforme (including Stevens-Johnson Syndrome), maculopapular, erythematous or eczematous eruptions, urticaria, rash, pruritis and Transient alopecia
Renal and urinary disorders	Not known	interstitial nephritis, yellow or brown discolouration of urine,
General disorders and administration site conditions	Not known	Asthenia, fever, chills, drug fever and arthralgia
Investigations	Not known	False positive urinary glucose

\*Acute pulmonary reactions are commonly manifested by fever, chills, cough, chest pain, dyspnoea, pulmonary infiltration with consolidation or pleural effusion on chest x-ray, and eosinophilia. In subacute pulmonary reactions, fever and eosinophilia occur less often than in the acute form.

Chronic pulmonary reactions occur rarely in patients who have received continuous therapy for six months or longer and are more common in elderly patients. Changes in ECG have occurred, associated with pulmonary reactions

\*\*Fatal events have been reported.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

## Symptoms

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

## Management

There is no known specific antidote. However, Nitrofurantoin can be hemodialyzed in cases of recent ingestion. Standard treatment is by induction of emesis or by gastric lavage. Monitoring of full blood count, liver function, and pulmonary function tests 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: Antibacterials for systemic use, Nitrofuran derivatives, ATC code: J01XE01

#### Mechanism of action

Nitrofurantoin is a broad-spectrum antibacterial agent, active against the majority of urinary pathogens. The wide range of organisms sensitive to the bactericidal activity include:

*Escherichia coli*

*Enterococcus Faecalis*

*Klebsiella Species*

*Enterobacter Species*

*Staphylococcus Species, e.g. S.Aureus, S.Saprophyticus, S.Epidermidis*

*Citrobacter Species*

Clinically most common urinary pathogens are sensitive to Nitrofurantoin. Most strains of *Proteus* and *Serratia* are resistant. All *Pseudomonas* strains are resistant.

### 5.2. Pharmacokinetic Properties

#### Absorption

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

#### Elimination

Maximum urinary excretion usually occurs 2-4 hours after administration of Nitrofurantoin. Urinary drug dose recoveries of about 40-45% are obtained. It has an elimination half-life of about 30 minutes

### **5.3. Pre-clinical Safety Data**

The available genotoxicity data indicate that nitrofurantoin is a mutagen. Two-year carcinogenicity studies in rats and mice reported carcinogenic effects. The relevance of the genotoxic and carcinogenic potential of nitrofurantoin to human is unknown. Extensive clinical use of nitrofurantoin over 65 years has not found any conclusive evidence for carcinogenic effects at therapeutic dosages.

In rats, at high doses a temporary halt in spermatogenesis was observed. No decreased fertility was observed in animal studies.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Furadantin Oral Suspension/ Nitrofurantoin Oral Suspension contains glycerol (E422), polysorbate-20, Carbomer, Saccharin sodium, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Sodium Hydroxide, flavourings (Lemon Essence F31874 and Apricot Flavour F31191) and purified water.

### **6.2. Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years

Use within 30 days after first opening

**6.4. Special precautions for storage**

Do not store above 25°C. Store in the original container in order to protect from light and moisture. Do not freeze.

**6.5. Nature and Content of Container**

This Suspension is supplied in 300ml amber glass bottles.

**6.6. Special precautions for disposal**

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

Furadantin suspension should be protected from light, as exposure will cause darkening of the active principle. Because of this, amber bottles should be used in dispensing.

**7 MARKETING AUTHORISATION HOLDER**

Mercury Pharmaceuticals Ltd,  
Dashwood House,  
69 Old Broad Street,  
London, EC2M 1QS,  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER(S)**

PL 12762/0055

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

31/03/2000

**10 DATE OF REVISION OF THE TEXT**

08/08/2025