

## 1. DETERMINATION OF THE MEDICINAL PRODUCT

### 1.1 Name: FUROLIN<sup>®</sup>

**1.2 Composition:** Active ingredient: Nitrofurantoin.

**Excipients:** Lactose monohydrate, Starch maize, Polyvidone, Magnesium stearate.

**1.3 Pharmaceutical form:** Tablets.

**1.4 Content:** Each tablet contains 100 mg of Nitrofurantoin.

**1.5 Description/Packaging:** Carton box containing 30 tablets in a PVC/Aluminum blister (3x10) and an instruction leaflet.

**1.6 Therapeutic category:** Anti-infective of urinary tract.

**1.7 Marketing Authorisation Holder - Cyprus Exceptional**

**Marketing Authorisation Holder - Manufacturer:**

**IASIS PHARMA**

137 Filis Ave., 134 51 Kamatero Attikis, Greece

Tel: +30 210 2311031

## 2. THINGS THAT YOU SHOULD KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

**2.1 General information:** Nitrofurantoin is an antibiotic with a broad spectrum antimicrobial activity.

**2.2 Indications:** It is indicated for the treatment of mild urinary tract infections, cystitis, prostatitis, postoperative infections and after prostatectomy.

**2.3 Contraindications:** FUROLIN<sup>®</sup> should not be used if there is any known hypersensitivity to the active substance or any of the excipients. Also, it should not be used in cases of lack of the enzyme glucose-6-phosphate dehydrogenase and in case of severe renal failure.

**2.4 Special warnings and precautions for use**

### 2.4.1 General:

Before the initiation of the treatment with FUROLIN<sup>®</sup>, make sure that your doctor is aware if:

- You have any disease of the liver or the kidneys.
- You drink alcohol regularly.
- You have other diseases.
- You have allergies.

### 2.4.2 Elderly:

- There are no special contraindications for elderly.

### 2.4.3 Pregnancy:

Before the initiation of the treatment, inform your doctor if you are pregnant or you intend to become pregnant.

### 2.4.4 Breast-feeding:

The safety of the medicine during lactation has not been established.

### 2.4.5 Children:

The medicine is not indicated for young children.

### 2.4.6 Effects on ability to drive and use machines:

There is not any known effect on the ability to drive or operate machinery.

### 2.4.7 Special warnings regarding the excipients:

The medicine should not be administered to patients with hypersensitivity to any of the components.

**2.5 Interaction with other medicinal products and other forms of interaction:**

Co-administration with probenecid increases the undesirable effects due to decreased elimination. Nalidic acid antagonizes the effect of Nitrofurantoin.

### 2.6 Posology and method of administration

One tablet 50-100 mg four times a day, according to your doctor's instructions.

### 2.7 Overdose:

In the event of overdose general supportive measures should be applied.

### 2.8 Undesirable effects:

Undesirable effects are possible to be noticed like headaches, dizziness, vomiting and, rarely, haematological changes.

### Reporting side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly to the:

• National Organization for Medicines, Mesogion Ave. 284,

15560 Chologos Greece, www.eof.gr

• Cyprus Pharmaceuticals Services, Ministry of Health, CY-1475,

www.moh.gov.cy/phs, Fax: +357 22608649.

By reporting side effects you can help provide more information on the safety of this medicine.

### 2.9 If you miss a dose:

If you miss a dose, continue with the next dose normally and consult your doctor.

### 2.10 Self life:

Since the package has not been opened and the correct storage conditions are held, the self life is indicated on the outer and inner packaging. Do not use this drug after the expiration date.

### 2.11 Special precautions for storage:

FUROLIN<sup>®</sup> must be stored at temperature below 25°C, protected from light.

### 2.12 Date of last product information leaflet revision:

September 2013.

## 3. INFORMATION ON THE RATIONAL USE OF DRUGS

- This medicine was prescribed by your doctor for your specific health problem. You should not administer it to others or use it yourself for other health problems, without prior consent from your doctor.
- Inform immediately your doctor or pharmacist if a problem appears during the treatment.
- If you have any questions regarding the medicine that you are taking or you need further information on your health problem, do not hesitate to contact your doctor or pharmacist and ask for additional information.
- The medicine that was prescribed to you is safe and effective only when administered according to your doctor or pharmacist instructions.
- It is important for your safety and your health to read carefully all information regarding the medicine that was prescribed to you.
- Do not store medicines in bathroom closets since heat and humidity may alter them and render them hazardous for your health.
- Do not store medicines that have already expired or are no more useful to you.
- For more safety keep medicines in a secure place away from children

## 4. MODE OF ADMINISTRATION

This medicine may only be administered with a doctor's prescription