IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA1441/002/001
Case No: 2045284

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Zambon S.p.A.

via Lillo del duca, 10, **20091-Bresso**, **Milano**, **Italy**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Monuril 2g Granules for Oral Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **26/02/2008** until **12/11/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Monuril 2 g Granules for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 6 g sachet contains 3.754 g fosfomycin-trometamol (1:1) equivalent to 2 g fosfomycin.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral solution.
Orange- mandarin flavoured granules

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of acute uncomplicated urinary tract infections due to sensitive organisms in adults.

4.2 Posology and method of administration

Adults only:
A single dose of 2 g taken on an empty stomach, preferably before bedtime, after bladder emptying. The contents of the sachet should be dissolved in water and the solution swallowed immediately.

Elderly patients:
Not recommended due to diminished urinary excretion.

Children:
There is insufficient clinical use in children to make a recommendation for usage.

4.3 Contraindications

Hypersensitivity to Fosfomycin. Monuril should not be used in patients with impaired renal function (creatine-clearance < 80 ml/min).

4.4 Special warnings and precautions for use

None stated

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of metoclopramide may decrease the urinary concentrations of fosfomycin, but a therapeutic concentration is still maintained.

4.6 Pregnancy and lactation

The safety of fosfomycin has not been established in pregnant women. There is, to date, no evidence from animal studies that fosfomycin is teratogenic.
Fosfomycin is excreted in human breast milk. Therefore Monuril has to be used with caution in lactating women.

4.7 Effects on ability to drive and use machines

No evidence exists that the drug can modify attention or reaction time.

4.8 Undesirable effects

The product may give rise to gastrointestinal upsets e.g. diarrhoea, nausea. Transient skin rash and headache have also occurred more rarely.

4.9 Overdose

When Monuril is supplied in packaging containing only one sachet, there is a remote risk of overdose. However, in case of overdose, it is sufficient to encourage the urinary elimination of the drug through adequate administration of oral fluids.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Broad spectrum antibiotic, with a bioavailability after fasting oral administration of 30-55%. Food taken concomitantly diminishes absorption and urinary excretion.

5.2 Pharmacokinetic properties

After a dose of 50 mg/kg (3 g in adult) peak urinary concentrations of 2000-3000 mcg/ml are reached at 2-4 h. Therapeutically active urinary concentrations are maintained for up to 36 h.

Elimination t ½ is 2.5-7 h, with 35-50% of an oral dose excreted in kidney via glomerular filtration.

Patients with diminished renal function have proportionately reduced excretion through kidney; urinary levels are generally inadequate for activity in these patients.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mandarin flavour,
Orange flavour,
Saccharin,
Sucrose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Sachets are a four layer laminate: paper, polyethylene, aluminium, polyethylene.
Sachets are supplied in cardboard outer containing either 1 sachet or 2 sachets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The dose must be dissolved in a glass of water and administered soon after dissolving.

7 MARKETING AUTHORISATION HOLDER

ZAMBON S.p.A.
via Lillo del Duca 10
20091 Bresso (MI) - Italy

8 MARKETING AUTHORISATION NUMBER

PA1441/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 November 1995
Date of last renewal: 13 November 2005

10 DATE OF REVISION OF THE TEXT

December 2007