

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0126/032/001

Case No: 2045663

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

Clonmel Healthcare Limited

Waterford Road, Clonmel, Co. Tipperary, Ireland

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

OXYTETRACYCLINE 250 Milligram Tablets

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 **28/03/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oxytetracycline 250 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Oxytetracycline equivalent to 250 mg Oxytetracycline Dihydrate.

Excipients: Lactose monohydrate 18.56mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated Tablet (tablet)

Yellow, biconvex, film-coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Oxytetracycline is indicated in the treatment of infections due to sensitive micro-organisms such as: acute and chronic bronchitis (including prophylaxis of acute exacerbations), broncho-pneumonia, atypical pneumonia caused by mycoplasma pneumonia, infected bronchiectasis, bronchiolitis, otitis media, Vincent's angina, urinary tract infections, non-gonococcal urethritis, gastro-intestinal and biliary tracts, soft-tissue infections, post-partum infections (endometritis), meningitis, endocarditis caused by reckettsiae or anaerobic streptococci, acne vulgaris, gonorrhoea and syphilis (if penicillin is unsuitable), granuloma inguinale, chancroid, brucellosis (usually in conjunction with streptomycin), cholera, amoebiasis (as an adjunct to specific treatment), typhus and Q-fever, psittacosis and lymphogranuloma venereum, trachoma (to supplement topical therapy).

4.2 Posology and method of administration

Adults:

250 mg or 500 mg by mouth every six hours for a period of five to ten days for most infections. However, respiratory infections such as acute exacerbation of bronchitis and pneumonia caused by mycoplasma should be treated with 500 mg four times daily.

For prophylaxis of respiratory infections, 250 mg two or three times daily is recommended. For gonorrhoea, syphilis, brucellosis and most diseases characteristically associated with tropical regions, the total daily dose is usually two or three grams, rarely more. Treatment should be continued for at least two days after symptoms have subsided and signs returned to normal.

Children: Oxytetracycline is not recommended for use in children under 12 years unless considered essential by the physician.

Elderly: The normal adult dose is appropriate. However, caution is advised in renally impaired patients.

NB: Absorption of oxytetracycline is reduced in the presence of milk or antacids containing divalent or trivalent metallic ions.

Route of administration

Oral.

4.3 Contraindications

1. Use in patients with advanced renal insufficiency.
2. Use in patients with hypersensitivity to tetracyclines.

4.4 Special warnings and precautions for use

1. Tetracyclines should only be administered with great caution in patients with hepatic insufficiency, or in those receiving potentially hepatotoxic drugs. Careful monitoring of dosage by serum levels is necessary.
2. Prolonged use of an anti-infective may result in the development of infection due to micro-organisms resistant to the anti-infective.
3. Tetracyclines are absorbed to some extent by developing bones and teeth and may produce staining and enamel hypoplasia. For this reason during the second half of pregnancy, lactation and breast feeding, and in children up to the age of twelve years, tetracyclines should only be administered if considered essential by the physician, and for as short a treatment as feasible. Repeated courses should be avoided. The effect appears to be related to total dosage given, and not only on the duration of treatment.
4. Tetracyclines should only be administered with great caution in patients with renal insufficiency and dosage may require reduction.
5. Cross-resistance between tetracyclines may develop in micro-organisms, and cross sensitisation in patients.
6. In severe illness or when treatment is prolonged, supplementary B-complex vitamins are recommended.
7. This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

1. Administration of tetracyclines with milk, antacids, calcium or iron preparations may affect absorption.
2. Tetracyclines may prolong the action of coumarin anti-coagulants, and per se delay coagulation.
3. Tetracyclines therapy should not be used in conjunction with penicillins.
4. Oral contraceptive efficacy may be decreased.

4.6 Pregnancy and lactation

Tetracycline cross the placental barrier and may have a toxic effect on the foetus. Special care should be exercised if administered during pregnancy. The use of tetracyclines in lactating women should be avoided if possible.

4.7 Effects on ability to drive and use machines

No information submitted.

4.8 Undesirable effects

Side effects include gastrointestinal upset (anorexia, nausea, vomiting diarrhoea), at times with monilial overgrowth, skin rashes, haematological disorders (haemolytic anaemia, thrombocytopenia and neutropenia) and photosensitivity.

High dose therapy may induce uraemia, however this is unlikely with dosage below 3 g daily and in normal renal function.

Extreme rare cases of raised intracranial pressure may occur in infants.

4.9 Overdose

Gastric lavage may be beneficial in the first hours after ingestion. Milk will reduce absorption.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic Group: Tetracyclines

ATC Code: J01AA

Broad spectrum antibiotic readily absorbed, concentrated in bile and excreted through urine and faeces.

5.2 Pharmacokinetic properties

Broad spectrum antibiotic readily absorbed, concentrated in bile and excreted through urine and faeces.

5.3 Preclinical safety data

No information submitted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

Maize Starch

Povidone

Sodium Laurilsulfate

Stearic Acid

Sodium Starch Glycolate

Film-coat (subcoat)

Opadry White OY-S-7211

Hypromellose 2910 (E464)

Titanium Dioxide (E171)

Hyprolose (E463)

Propylene Glycol

Film-coat (colour coat)

Opadry Yellow OY-S-6460

Hypromellose 2910 (E464)

Purified Talc

Quinoline Yellow Aluminium Lake (E104)

Titanium Dioxide (E171)

Propylene Glycol

Erythrosine Aluminium Lake (E127)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the container tightly closed.

Store in the original container.

6.5 Nature and contents of container

PP tablet containers with LDPE caps. High density polyethylene film may be used as packing material.

Pack sizes: 50, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Limited

Waterford Road

Clonmel

Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 126/32/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 March 1988

Date of last renewal: 28 March 2008

10 DATE OF REVISION OF THE TEXT

July 2008