SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oxytetracycline Tablets BP 250 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains oxytetracycline dihydrate 250 mg
Excipients with known effect: Oxytetracycline Tablets contain 152.50mg of sucrose and 5.560mg of Mastercote Yellow (sodium benzoate).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet, coated.

Yellow, deep convex, sugar, coated tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oxytetracycline tablets are indicated in the treatment of infections caused by oxytetracycline-sensitive organisms. These include chronic bronchitis, pneumonia, urinary tract infections, brucellosis, pertussis, rickettsial fevers and psittacosis.

4.2 Posology and method of administration

Oxytetracycline should be given one hour before or two hours after meals, since food and some dairy products interfere with absorption. Therapy should be continued for up to three days after symptoms have subsided.

Route of administration: Oral.

Adults and children over 12: One tablet four times a day. This may be increased to 6 or 8 tablets daily in severe infections.

Children: Not recommended for children under 12 years

Elderly: Oxytetracycline tablets 250 mg should be used with caution in the treatment of elderly patients where accumulation is a possibility.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1
Must not be given to children under 12 years.
Chronic renal or hepatic dysfunction.
Pregnancy or breastfeeding.
Systemic lupus erythematosus (SLE).
Patients receiving vitamin A or retinoid therapy.

4.4 Special warnings and precautions for use

Tetracycline drugs may cause permanent tooth discoloration (yellow-grey-brown), if administered during tooth development, in the last half of pregnancy and in infancy up to twelve years of age. Enamel hypoplasia has also been reported. This adverse reaction is more common during long-term use of the drug but has been observed following repeated short-term courses

The anti-anabolic action of tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired renal function, higher serum levels of Oxytetracycline may lead to azotaemia, hyperphosphataemia and acidosis.

Absorption is adversely affected by milk, antacids and aluminium, calcium, iron, magnesium and zinc salts.

Tetracyclines depress plasma prothrombin activity, therefore reduced dosages of concurrent anticoagulants may be required.

When treating venereal disease, where co-existent syphilis is suspected, proper diagnostic procedures should be utilised. In all such cases monthly serological tests should be made for at least four months.

The use of antibiotics may occasionally result in the overgrowth of non-susceptible organisms including Candida. Constant observation of the patients is essential. If a resistant organism appears, the antibiotic should be discontinued and appropriate therapy instituted.

In long term therapy, periodic laboratory evaluation of organ systems, including haematopoietic, renal and hepatic studies should be performed.

High doses of tetracyclines have been associated with a syndrome involving fatty liver degeneration and pancreatitis.

The use of tetracyclines in general is contraindicated in renal impairment due to excessive systemic accumulation and used with caution in patients with hepatic impairment or those receiving drugs which may have hepatotoxic effects; high doses should be avoided.

Care is advised when administering to patients with myasthenia gravis.

Treatment should cease if symptoms of benign intracranial hypertension (e.g. headache
and visual disturbance) develop.

Photosensitivity reactions may occur in hypersensitive persons and such patients should be warned to avoid direct exposure to natural or artificial sunlight and to discontinue therapy at the first sign of skin discomfort.

Use in the elderly: Special care should be taken when treating the elderly.

Patients with rare heredity problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Oxytetracycline contains sodium benzoates which may increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of oxytetracycline may be impaired by antacids and preparations containing aluminium, calcium, iron, magnesium or zinc. Allow two to three hours between doses of oxytetracycline and antacids.
Some foods and dairy products may interfere with absorption.

Anti-diarrhoeal preparations such as kaolin-pectin and bismuth subsalicylate hinder absorption of tetracyclines.

Combination of tetracyclines with diuretics may be detrimental to renal function.

There have been reports of nephrotoxicity (increased blood urea nitrogen and serum creatinine) and death in some cases when oxytetracycline therapy has been combined with methoxyflurane or other drugs known to be nephrotoxic.

Since oxytetracycline has been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require a downward adjustment

of their anticoagulant dose. Oxytetracycline may prolong the action of coumarin anticoagulants.

An increased incidence of benign intracranial hypertension has been reported when retinoids, Vitamin A and tetracyclines are used concomitantly and therefore concurrent use is contraindicated.

A few cases of pregnancy or breakthrough bleeding have been attributed to the concurrent use of oxytetracycline with oral contraceptives and alternate contraceptive advice should be sought where necessary.

Oxytetracycline should not be given concurrently with bactericidal drugs such as Penicillins as bacteriostatic drugs may interfere with the bactericidal action of penicillin.

Oxytetracycline may increase the hypoglycaemic effects of insulin and sulphonylureas in patients with diabetes mellitus.

4.6 Fertility, pregnancy and lactation

Pregnancy
Should not be used during pregnancy unless considered essential. Tetracyclines cross the placenta and may have toxic effects on foetal tissue, particularly on skeletal development. The use of tetracycline compounds during pregnancy has been associated with reports of maternal liver toxicity. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be appraised of the potential hazard to the foetus.

Breast-feeding
Tetracyclines are excreted in breast milk and are therefore contra-indicated in nursing mothers.

Use in newborns, infants and children
All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was reversed when the drug was discontinued.

4.7 Effects on ability to drive and use machines

No or Negligible influence.

4.8 Undesirable effects

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); Frequency not known (cannot be estimated from the available data).

Blood and lymphatic disorders:
Frequency not known: haemolytic anaemia, thrombocytopenia, neutropenia and eosinophilia.

Endocrine disorders:
Frequency not known: brown-black microscopic discolouration of thyroid tissue in use over prolonged periods. (No abnormalities of thyroid function are known to occur).

Nervous system disorders:
Frequency not known: bulging fontanelles in infants, benign intracranial hypertension
If raised intracranial pressure occurs treatment with oxytetracycline should be stopped.

Cardiac disorders:
Frequency not known: pericarditis.

Gastro-intestinal disorders:
Rare: oesophagitis and oesophageal ulceration (reported in patients taking capsules or tablets forms of drugs in the tetracyclines class. Most of these patients took medication immediately before going to bed.

Frequency not known: Gastro-intestinal irritation giving rise to nausea, abdominal discomfort vomiting, diarrhoea, anorexia, dysphagia (if GI irritation occurs, tablets should be taken with food), Pseudomembranous colitis, intestinal overgrowth of resistant organisms (Candida albicans, in particular), may occur and cause glossitis, rectal and vaginal irritation and inflammatory lesions (with candidial overgrowth) in the anogenital regions.

Similarly, resistant staphylococci may cause enterocolitis. Tooth discolouration, pancreatitis.

Hepatobiliary disorders:
Frequency not known: Hepatotoxicity (hepatitis, jaundice, hepatic failure), fatty liver degeneration.

Skin and subcutaneous tissue disorders:
Uncommon: exfoliative dermatitis.
Frequency not known: macropapular and erythematous rashes, photo-erythema (Patients exposed to direct sunlight or ultraviolet light should be advised to discontinue treatment if any skin reaction occurs),
Hypersensitivity reactions: urticaria, angioneurotic oedema, anaphylaxis, anaphylactoid purpura, pericarditis, exacerbation of systemic lupus erythematosus.

Renal and urinary disorders:
Frequency not known: renal dysfunction.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

There are no specific overdose problems or symptoms. Gastric lavage and administration of milk or antacids may be employed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, tetracylines, ATC code: J01A A06
Oxytetracycline is a broad-spectrum tetracycline antibiotic with activity against a large number of gram positive and gram-negative bacteria. It acts by interfering with bacterial protein synthesis.

5.2 Pharmacokinetic properties

Oxytetracycline is absorbed irregularly and incompletely from the GI tract. Absorption may be affected by food, drink and other medicines. It should preferably be given before food and milk drinks, and antacids and iron containing medicines should be avoided.

In circulation, oxytetracycline is bound to plasma proteins (20-35%) and it is also widely distributed in body tissues and fluids. The biological half-life is in the order of $9_{1/2}$ hours and excretion is in the urine and faeces.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc
Maize starch
Sodium lauryl sulphate
Magnesium stearate

Coating

Talc
Kaolin heavy
Shellac
Sucrose
Dextrin
Gelatin
Nipasept sodium containing sodium methyl, sodium ethyl and sodium propyl hydroxybenzoate (E219, E215 and E217)
Titanium dioxide (E171)
Mastercote Yellow SP 2152 containing sodium benzoate (E211), sunset yellow FCF (E110), quinoline yellow (E104) and indigo carmine (E132)

6.2 Incompatibilities

None

6.3 Shelf life

As packaged for sale:

5 years - in plastic containers
2 years - in blister packs

6.4 Special precautions for storage

Keep out of the reach of children.
Store below 25°C, protect from light and moisture.

6.5 Nature and contents of container

1. Opaque plastic containers composed of polypropylene tubes and polyethylene made tamper evident or child resistant tamper evident closures with a packing inclusion of either standard polyether foam or polyethylene or polypropylene made filler in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 50, 56, 84, 100, 250, 500 and 1000 tablets.

2. Blister packs of aluminium/opaque PVC. It is subsequently packed in printed boxboard cartons in pack sizes of 9, 10, 14, 15, 20, 21, 28, 30, 56 and 84 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No specific instructions for use/handling

7 MARKETING AUTHORISATION HOLDER

Relonchem Limited,
Cheshire House,
Gorsey Lane,
Widnes, WA8 0RP

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0134

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22 April 2004

10 DATE OF REVISION OF THE TEXT

09/02/2022