SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Oxytetracycline Tablets BP 250 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablets contains Oxytetracycline 250.0 mg (as dihydrate).

Excipients with known effect:
Lactose 13.44 mg, Sucrose 180 mg, Tartrazine (E102) approximately 0.24 mg.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Coated tablet.

Round, yellow, sugar coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of infections due to Chlamydia, Brucella, Mycoplasma, Rickettsia, and other sensitive organisms. May also be used for prophylaxis and treatment of chronic bronchitis, non-gonococcal urethritis, gonorrhoea, syphilis, other urinary tract infections and severe acne vulgaris.

4.2 Posology and method of administration

Posology
The tablets should preferably be taken on an empty stomach (1 hour before food or 2 hours after).

Adults, the elderly and children over 12 years: Normal dose is 250 – 500 mg every 6 hours (4 times a day). This may be increased in severe infections.

For acne the dose is usually 250 mg three times a day for 4 weeks, but this may be prolonged if necessary.

Children under 12 years of age: Not to be given.

Method of administration
For oral administration.

4.3 Contraindications

Must not be given to children under 12 years.
Known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Chronic renal or hepatic dysfunction.
Porphyria
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 nonsusceptible 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.

This medicine contains:
Lactose and sucrose. Patients with rare hereditary problems of fructose or galactose intolerance, total lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Tartrazine (E102), which may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

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 contrainidicated.

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.

Oxytetracycline may cause an increase in serum lithium levels when taken concomitantly with lithium-containing medications (e.g. antidepressants/medicines to treat bi-polar disorder). The lithium dosage should either be adjusted or concomitant treatment stopped, as appropriate.

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 discoloration 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

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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

Lactose
Pregelatinised Maize Starch
Sodium Laurilsulfate
Gelatin
Magnesium Stearate
Talc
Sucrose
Titanium Dioxide E171
Yellow colour containing Dried Aluminium Hydroxide & Tartrazine (E102).
Wax polish (consisting of Beeswax, Carnauba Wax, Shellac and Industrial Methylated Spirit)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Tablet containers: Do not store above 25°C. Keep the container tightly closed.

Blister packs: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

HDPE tablet containers with LDPE caps of 1000 tablets.

Al/PVC blisters enclosed in an outer carton.

Pack sizes: 28, 56 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Kent Pharma UK
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Connect 38, 1

Dover Place,
Ashford, Kent,
England, TN23
1FB.

8. MARKETING AUTHORISATION NUMBER(S)

PL 51463/0132

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/01/2006

10. DATE OF REVISION OF THE TEXT

21/08/2023