SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

OXYMYCN/Oxytetracycline Capsules 250 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxytetracycline Hydrochloride BP 265 mg

3 PHARMACEUTICAL FORM

Capsule

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Infections caused by oxytetracycline-sensitive organisms. These include acute and chronic bronchitis, pneumonia, urinary tract infections, brucellosis, pertussis, rickettsial fevers and psittacosis.

4.2 Posology and method of administration

Capsules should be swallowed whole with water one hour before or two hours after a meal.

Adults and children of 12 years and above 250 mg every six hours. Dosage may be increased in severe infections to 250 mg every three hours after an initial loading dose of 1 g.

Children: Not recommended for children under 12years of age.

Elderly: May be given at the usual adult dosage. The possibility of sub-clinical renal insufficiency should be kept in mind, as it may lead to drug accumulation.

Therapy should be continued for at least 24 - 48 hours after symptoms and fever have subsided.

4.3 Contraindications

Known hypersensitivity to tetracyclines. Renal impairment. Children under 12 years of age. Use during pregnancy or lactation.

4.4 Special warnings and precautions for use

Medicines and foods containing di-/tri-valent cations interfere with the absorption of oxetetracycline and doses should be maximally seperated.. If however, gastric irritation occurs the medicine should be taken with food.

OXYMYCIN should be used with caution in patients with hepatic or renal dysfunction, or in conjunction with other potentially hepatotoxic or nephrotoxic drugs.

OXYMYCIN should not be administered to children during the period of tooth development because of the likelihood of staining of teeth and deposition in the epiphysis.

Intestinal overgrowth of resistant organisms (candida albicans in particular) may occur.

Photosensitivity reactions can sometimes occur. Susceptible patients should avoid direct exposure to natural or artificial sunlight and discontinue therapy at the first sign of skin discomfort.

Weak neuromuscular blockade mat occur in patients suffering from Myasthenia Gravis.
Exacerbation of SLE (systemic lupus erythematosus) may occur.

OXYMYCIN is unsafe in acute porphyrias.

4.5 Interaction with other medicinal products and other forms of interaction

Tetracyclines bind to di-/tri-valent cations. Absorption from the gastrointestinal tract is impaired by the concomitant administration of iron, calcium,aluminium, magnesium, bismuth and zinc salts(interactions with specified salts, antacids Bismuth containing ulcer-healing drugs, quinapril which may contain a magnesium carbonate excipienta). Dosages should be maximally separated.

Absorption of tetracyclines is impaired by food, milk and milk products.

The concomitant use of tetracycline mat reduce the efficacy of oral contraceptives and the concomitant use of retinoids may increase the risk of benign intracranial nypertension. It is advisable to avoid giving tetracyclines in conjunction with penicillin.

Patients reciving concurrent anti-coagulant therapy should have the doses of those drugs reduced because tetracycline depresses plasma prothrombin activity.
Atovaquone plasma concentration is reduced by teracycline.

Diuretics may aggravate nephrotoxicity by volume depletion.

4.6 Pregnancy and lactation

Do not use in pregnancy unless there are compelling reasons.

4.7 Effects on ability to drive and use machines

Does not affect ability to drive and use machines.

4.8 Undesirable effects

Nausea, vomiting, diarrhoea, anorexia and on rare occasions dysphagia have been reported.

Skin reactions have been occasionally occurred. The most common reaction is photosensitivity. Erythematous, and macro-papular rashes, pruritis, bullous dermatoses and exfoliative dermatitis have also been reported.

A few cases of pancreatitis and antibiotic-associated colitis have beeb reported. Oesophagitis and oesophageal ulceration have been reported, usually when taken beforw bed or without inadequate fluids. Hypersensitivity reactions reactions include rash, exfoliative dermatitis, urticaria, angioedema, anaphylaxis, pericarditis and exacerbation of systemic lupus erythematosus.

Teeth discolouration has occurred, but is usually only obvious after repeated doses.

Bulging fontanelles and benign intracranial hypertension in juveniles and adults have been reported indicated by headache and visual disturbances including blurring of vision, scotomata and diplopia. Permanent visual loss has been reported.

Overgrowth of resistant organisms may cause candidiasis, pseudomembrananous colitis (Clostridium difficile overgrowth), glossitis, stomatitis, vaginitis and staphylococcal entero-colitis.

On rare occasions transient increases in liver function tests, hepatitis, jaundice and hepatic failure have been reported. Blood dycrasias have also occurred.

4.9 Overdose

Although overdosage with antibiotics is rare, if it should occur gastric lavage supportive therapy and control of plasma electrolytes is indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxytetracycline is primarily a bacteriostatic antibiotic and has a similar spectrum of activity to other tetracyclines.

Oxytetracycline is a broad spectrum antibiotic to sensitive organisms.

5.2 Pharmacokinetic properties

Oxytetracydline is absorbed irregularly to the extent of about 60% of an oral dose, absorption occurring in the stomach and upper small intestine.

Peak plasma concentrations achieved 2-4 hours after an oral dose.

The mean plasma half-life is 9.2 hours. The plasma/protein bind is 27-35%. The drug is eliminated largely unchanged mostly in the urine, with some in the faeces. A small amount is metabolised in the liver.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc
Alginic acid
Stearic acid
Sodium lauryl sulphate

Capsule shell size 1:
Gelatin
Titanium dioxide
Yellow iron oxide

6.2 Incompatibilities

Antacids containing aluminium, magnesium or calcium, interfere with the absorption of oxytetracycline as does the calcium content of milk.

6.3 Shelf life

36 Months.

6.4 Special precautions for storage

Store below 25°C in a dry place. Keep containers well closed.
Protect from light.

6.5 Nature and contents of container

High density polystyrene or polypropylene containers with polypropylene or polythene lids and polyurethane/polythene inserts.

Pack sizes: 100 and 500 capsules

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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NICOSIA

CYPRUS

P.C. 1060

CYPRUS

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PL 33414/0074

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June 1972 19/06/1996

10 DATE OF REVISION OF THE TEXT

10/01/1996