SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oxytetracycline 250mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxytetracycline 250mg (as dihydrate)
For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Coated tablet
Yellow, round, bi-convex, sugar coated.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The treatment of infection due to chlamydia, Brucella, Mycoplasma, Rickettsia and other sensitive organisms.

It can also be used in the prophylaxis and treatment of chronic bronchitis, non gonococcal urethiritis, gonorrhoea, syphilis, urinary tract infection and severe acne vulgaris.

4.2 Posology and method of administration

The tablets are for oral administration and the normal dose is 250-500mg every six hours
(4 times a day). This may be increased in severe infections.

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

The tablets are best taken on an empty stomach (1 hour before food or two hours after).
The above regimen is suitable for adults and the elderly.

The tablets must not be given to children below the age of 12.

4.3 Contraindications

Must not be given to children below 12 years. Hypersensitivity, renal or hepatic impairment, pregnancy, porphyria, and systemic lupus erythematosus (SLE).

4.4 Special warnings and precautions for use

Absorption is adversely affected by milk, antacids and zinc and iron salts. Tetracyclines depress plasma prothrombin activity, therefore reduced dosages of concurrent anticoagulants may be required. Lower doses are indicated in cases of renal impairment to avoid excessive systemic accumulation and if therapy is prolonged serum level determinations are advisable. Special care should be taken when treating the elderly or patients receiving potentially hepatotoxic drugs. Not to be used with penicillins and discontinue treatment if supra infection develops.

4.5 Interaction with other medicinal products and other forms of interaction

Oxytetracycline may potentiate action of some anti-coagulants. Antacids, Iron and Zinc salts, dairy products and food may interfere with absorption. There is a slight risk of adverse effect on oral contraception.

4.6 Fertility, Pregnancy and lactation

The product should not be used unless absolutely essential as use of Tetracyclines during teeth development may bring about permanent discolouration.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Photosensitivity and dermatological reactions are rare, G.I. disturbances e.g. vomiting or diarrhoea may occur. As with all antibiotics, overgrowth of resistant organisms may cause stomatitis, glossitis, vaginitis or enterocolitis. Candidiasis has also been seen.

Occurrences of enamel hypoplasia have been reported and bulging fontanelles in infants and benign intercranial hypertension in adults has also been seen. Treatment should cease if evidence of raised intercranial pressure develops.

4.9 Overdose

No specific overdose problems or symptoms. Gastric lavage and administration of milk or antacids.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxytetracycline is a broad spectrum tetracycline antibiotic with activity against a large number of gram positive and gram negative bacteria.

The product acts by interfering with bacterial protein synthesis.

5.2 Pharmacokinetic properties

Oxytetracycline is absorbed from the GI tract irregularly and incompletely. Absorption may be affected by food, drinks and other medication.

It should preferably be given before food and milk drinks, antacids and iron containing medicines should be avoided.

In circulation oxytetracycline is bound to plasma proteins (20-35%) and is also widely distributed in body tissues and fluids.

Biological half life is in order of 91/2 hours. Excretion is in urine and faeces.

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet Core:
Lactose

Potato Starch
Sodium Lauryl Sulphate
Gelatin
Magnesium Stearate

Tablet Coat
Talc
Gelatin
Sucrose
Titanium Dioxide (E171)
Tartrazine Aluminium Lake (E102)

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.

6.5 Nature and contents of container

Securitainer - high density polyethylene bottle - low density polyethylene caps
Pack size: 1000 tablets

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Activase Pharmaceuticals Limited,

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Nicosia.

Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 28444/0091

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th January 2005

10 DATE OF REVISION OF THE TEXT

11/01/2012