Approved Professional Information for Medicines for Human Use:
MOXYMAX 250/500/S/SF

SCHEDULING STATUS

S4

PROPRIETARY NAME (AND DOSAGE FORM):

Moxymax 250 (capsules)

Moxymax 500 (capsules)

Moxymax S (powder for suspension)

Moxymax SF (powder for suspension)

COMPOSITION:

Amoxycillin trihydrate BP available as:

Moxymax 250 - Gelatin capsules containing the equivalent of 250 mg amoxycillin.

Moxymax 500 - Gelatin capsules containing the equivalent of 500 mg amoxycillin.

Moxymax S Each 5 ml of the reconstituted suspension contains the equivalent of 125 mg amoxycillin.

Contains sugar: Sucrose 3 068,18 mg.

Moxymax SF Each 5 ml of the reconstituted suspension contains the equivalent of 250 mg amoxycillin.

Contains sugar: Sucrose 2910,362 mg.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins.

PHARMACOLOGICAL ACTION:

Amoxycillin is a penicillinase-susceptible penicillin. Amoxycillin exhibits in-vitro bactericidal activity against a wide range of Gram-negative and Gram-positive organisms including: (In-vitro sensitivity does not necessarily imply in vivo efficacy).

Gram-positive bacteria:

* Staphylococcus aureus

(Penicillin-sensitive)

Streptococcus pyogenes

* Streptococcus viridans

* Streptococcus faecalis

* Streptococcus pneumoniae

* Corynebacterium species

* Clostridium species

* Bacillus anthracis

Gram-negative bacteria:

Neisseria gonorrhoeae

Neisseria meningitidis

** Haemophilus influenzea

Bordetella pertussis

* Escherichia coli

Salmonella typhi

Salmonella species

Shigella species

Brucella species

Proteus mirabilis

*Sensitivity tests must be performed.

** Except 8-strains causing meningitis in children.

Amoxycillin is well absorbed orally. After oral administration, there is no significant difference between the peak serum levels in fasting and non-fasting subjects. The presence of food does not interfere with the absorption of amoxycillin and may therefore, be taken with meals. There is a linear/dose response in peak serum levels after oral administration. There is insufficient evidence at present to show that **Moxymax** penetrates into the cerebro-spinal fluid in therapeutic quantities and it should, therefore, not be used in the treatment of cerebrospinal infections.

Approximately 60 % of an oral dose of amoxycillin is excreted unchanged in the active form into the urine within six hours.

INDICATIONS:

Infections caused by susceptible, non-penicillinase-producing organisms including:

Upper respiratory tract infections.

Lower respiratory tract infections.

Otitis media

Upper urinary tract infections

Lower urinary tract infections

Skin & soft tissue infections

Gonorrhoea

Non-specific urethritis

Typhoid fever

Gastro-intestinal tract infections.

CONTRA INDICATIONS:

Allergy to penicillins or any of the cephalosporins . Patients with infectious mononucleosis since they are especially susceptible to amoxycillin induced skin rashes; patients with lymphatic leukaemia and patients with hyperuricaemia being treated with allopurinol may also be at an increased risk of developing skin rashes.

DOSAGE AND DIRECTIONS FOR USE:

The average adult dose for **Moxymax** is 750 mg- 1 ,5 g per day.

A. GENERAL DOSAGES:

To reconstitute pack size of 75 ml suspension, add 43 ml water; and for the 100 ml suspension, add 57 ml water. Invert the bottle and shake until all the powder is dispersed.

Adults: 250 mg (1 x 250 mg capsule or 5 ml of 250 mg/5 ml suspension)

three times a day.

500 mg (1 x 500 mg capsule) three times a day.

Children 2- 10 years: 125 mg (5 ml of 125 mg/5 ml suspension) three times a day.

Children 6 months- 2 years: 125 mg (2 ,5 ml of 125 mg/5 ml suspension) three times a day.

B. SPECIFIC DOSAGES:

Gastro-intestinal tract infections:

Adults: 1 to 2 g daily for 4 to 5 days.

Acute Typhoid Fever:

Adults: 4 g daily for 14 days.

Children: 100 mg/kg for 21 days.

Gonorrhoea:

Adults: 2 to 3 g at once.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Gastro-intestinal disturbances, including diarrhoea, nausea and vomiting occur frequently. Allergic reactions may occur, presenting as a pruritic skin rash, an erythematous skin reaction or urticaria. In this event withdrawal of **Moxymax** is necessary. Should a serious anaphylactic reaction occur, **Moxymax** should be discontinued and the patient treated with: Adrenalin, corticosteroids and antihistamines. Treatment With **Moxymax** may give rise to maculopapular rash, during or within a few days of completing treatment. The incidence of maculopapular rash is higher in patients

with infective mononucleosis. Pseudomembranous collitis has been reported. Super-infections with non-susceptible organisms may occur. Caution must be exercised in treating patients with dehydration or aliguria because of the possibility of crystalluria. The use of this antibiotic may lead to the appearance of resistant strains of organisms and sensitivity testing should, therefore, be carried out wherever possible, to ensure the appropriateness of the therapy.

SPECIAL PRECAUTIONS:

The dose should be reduced in patients with renal failure. Caution is needed when administering **Moxymax** to patients with syphillis, as the Jarisch-Herxheimer reaction may occur in these patients. **Moxymax** may decrease the efficacy of oestrogen - containing oral contraceptives. Due to **Moxymax's** effect on intestinal flora, the absorption of other medicines may be affected..

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See side-effects and special precautions. Treatment is symptomatic and supportive.

IDENTIFICATION:

Moxymax 250 Opaque/maroon, flesh coloured capsules.

Moxymax 500 Opaque/maroon, flesh coloured capsules

Moxymax S Free-flowing, creamy-white powder. Creamy-white suspension.

Moxymax SF Free-flowing, creamy-white powder. Creamy-white suspension

PRESENTATION:

Moxymax 250 Containers containing 15, 100 or 500 x 250 mg amoxycillin capsules, or Aluminium/PVC blister packs containing 15 amoxycillin capsules, packed in a cardboard carton.

Moxymax 500 Containers containing 15, 100 or 500 x 500 mg amoxycillin capsules, or Aluminium/PVC blister packs containing 15 amoxycillin capsules, packed in a cardboard carton.

Moxymax S Amber or clear glass bottles containing powder for reconstitution to 75 ml or 100 ml of 125 mg/5 ml suspension.

Moxymax SF Amber or clear glass bottles containing powder for reconstitution to 100 ml of 250 mg/5 ml suspension.

STORAGE INSTRUCTIONS:

Store below 25^{o}C in a dry place.

The reconstituted suspension must be used within 14 days if stored in a refrigerator or within 7 days if stored below 25 oc.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

Moxymax 250 28/20.1.2/0412

Moxymax 500 28/20.1.2/0413

Moxymax S 28/20.1.2/0414

Moxymax SF 28/20.1.2/0415

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