Approved Professional Information for Medicines for Human Use: MOXYMAX

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.

The other ingredients are: Sodium lauryl sulphate and pregelatinised starch (Starch 1500).

The composition of the hard gelatin capsule shell is: Gelatin, brilliant blue (CI 42090), erythrosine (CI 45430), quinolone yellow (CI 47005), sunset yellow (CI 15985), titanium dioxide (CI 77891), printing ink - HV white ink, printing ink – Opacode S-1-7020.

MOXYMAX 500 – Gelatin capsules containing the equivalent of 500 mg amoxycillin.

The other ingredients are: Sodium lauryl sulphate and pregelatinised starch (Starch 1500).

The composition of the hard gelatin capsule shell is: Gelatin, brilliant blue (CI 42090), erythrosine (CI 45430), quinolone yellow (CI 47005), sunset yellow (CI 15985), titanium dioxide (CI 77891), printing ink - HV white ink, printing ink – Opacode S-1-7020.

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

Contains sucrose (sugar).

The other ingredients are: Grape flavour, sodium acid citrate, sodium carboxymethylcellulose and sodium citrate.

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

Contains sucrose (sugar).

The other ingredients are: Grape flavour, sodium acid citrate, sodium carboxymethylcellulose and sodium citrate.

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:	**Gram-negative bacteria:**
* *Staphylococcus aureus* (penicillin-sensitive)	**Neisseria gonorrhoeae*
Streptococcus pyogenes	*Neisseria meningitides*
**Streptococcus viridans*	***Haemophilus influenzae*
**Streptococcus faecalis*	*Bordetella pertussis*
**Streptococcus pneumoniae*	**Escherichia coli*
**Corynebacterium species*	*Salmonella species*
**Clostridium species*	*Shigella species*
**Bacillus anthracis*	*Proteus mirabilis*

*Sensitivity tests must be performed.

**Except B-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 cerebrospinal fluid in therapeutic quantities and It should, therefore, not be used in the treatment of cerebrospinal infections.

Approximately 60 % of an oral dose of amoxicillin is excreted unchanged in the active form in 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 and soft tissue infections

Gonorrhoea

Non-specific urethritis

Typhoid fever

Gastro-intestinal tract infections

CONTRAINDICATIONS:

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

WARNINGS AND SPECIAL PRECAUTIONS

The dose should be reduced in patients with renal failure. Caution is needed when administering **Moxymax** to patients with syphilis, 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.

INTERACTIONS:

Moxymax may decrease the efficacy of oestrogen-containing oral contraceptives.

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/5ml 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/5ml suspension) three times a day.

Children 6 months - 2 years:

125 mg (2,5 ml of 125 mg/5ml 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:

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 colitis has been reported. Super-infections with non-susceptible organisms may occur.

Caution must be exercised in treating patients with dehydration or oliguria 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side Effects”. 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. White polyethylene capsule envelopes (Patient Ready Packs) containing 15 amoxycillin capsules.

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. White polyethylene capsule envelopes (Patient Ready Packs) containing 15 or 30 amoxycillin capsules.

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 at or below 25 °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 at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

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

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Austell Pharmaceuticals (Pty) Ltd

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

Moxymax Capsules: 12 January 1994

Moxymax Suspension: 16 February 1994