Approved Patient Information Leaflet for Medicines for Human Use: MOXYMAX

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MOXYMAX 250

Capsules

MOXYMAX 250 – Each capsule contains amoxycillin trihydrate equivalent to 250 mg amoxycillin.

MOXYMAX 500

Capsules

MOXYMAX 500 – Each capsule contains amoxycillin trihydrate equivalent to 500 mg amoxycillin.

MOXYMAX S

Powder for Suspension

Each 5 ml reconstituted suspension contains amoxycillin trihydrate equivalent to 125 mg amoxycillin.

MOXYMAX SF

Powder for Suspension

Each 5 ml reconstituted suspension contains amoxycillin trihydrate equivalent to 250 mg amoxycillin.

Read this leaflet carefully before you start taking MOXYMAX:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MOXYMAX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MOXYMAX CONTAINS:

The active substance is amoxicillin trihydrate.

MOXYMAX 250 – Each capsule contains amoxycillin trihydrate equivalent to 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 – Each capsule contains amoxycillin trihydrate equivalent to 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 reconstituted suspension contains amoxycillin trihydrate equivalent to 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 reconstituted suspension contains amoxycillin trihydrate equivalent to 500 mg amoxycillin.

Contains sucrose (sugar).

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

2. WHAT MOXYMAX IS USED FOR:

MOXYMAX belongs to a class of antibiotics called ‘penicillins’. MOXYMAX is used to treat infections caused by bacteria that are susceptible to amoxicillin.

These include:

- bronchitis,
- pneumonia,
- tonsillitis,
- sinusitis,
- middle ear infection,
- gynaecological infections,
- urinary tract infections,
- typhoid fever,
- duodenal ulcers caused by *H. pylori* infection.

3. BEFORE YOU TAKE MOXYMAX:

Do not take MOXYMAX:

- If you are hypersensitive (allergic) to amoxycillin or any of the ingredients of MOXYMAX or if you are allergic to any penicillin-type medicine or any of the cephalosporins.
- If you have glandular fever (infectious mononucleosis).
- If you have cancer of the blood (lymphatic leukemia).
- If you have high amounts of uric acid in the blood and are taking allopurinol (a medicine used to treat gout).

Take special care with MOXYMAX:

- If you suffer from kidney problems as you may need a lower dose.
- If you have syphilis, as use of MOXYMAX may cause a severe and serious adverse reaction called the Jarisch-Herxheimer reaction.

- Prolonged use may result in overgrowth of non-susceptible organisms causing a super-infection.
- If you are dehydrated or are passing very little urine, MOXYMAX may cause urine crystals which can be painful and irritating.

Taking MOXYMAX with food and drink:

It may be taken before, during or after your meals.

Pregnancy and Breast-feeding:

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

MOXYMAX is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of MOXYMAX:

MOXYMAX contains sucrose (a sugar). Please inform your doctor if you have an intolerance to any sugars.

Taking other medicines with MOXYMAX:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

MOXYMAX may reduce the effectiveness of the oral contraceptive pill, and you should therefore take extra precautions e.g. use a condom during your treatment.

4. HOW TO TAKE MOXYMAX:

Do not share medicines prescribed for you with any other person.

Always take MOXYMAX exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with MOXYMAX will last. Do not stop treatment early because your infection may not clear up.

If you have the impression that the effect of MOXYMAX is too strong or too weak, talk to your doctor or pharmacist.

The usual dose for an adult is 750 mg (3 capsules) – 1.5 g (6 capsules) per day.

General dosages:

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.

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.

If you take more MOXYMAX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of MOXYMAX:

If you missed a dose, take the dose as soon as you remember, but do not take your next dose at the same time. Then go on as before. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

MOXYMAX can have side effects.

Not all side effects reported for MOXYMAX are included in this leaflet. Should your general health worsen or if you experience any untoward effect while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MOXYMAX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MOXYMAX. You may need urgent medical attention or hospitalisation

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty or breathing, discoloured spots (rashes) on the surface of the skin,
- rash or itchy skin.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- diarrhoea,
- nausea (feeling sick),
- vomiting,
- crystals in the urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF THIS MEDICINE

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.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date stated on the label.

7. 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.

8. 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.

9. 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

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Austell Pharmaceuticals (Pty) Ltd

1 Sherborne Road

Parktown

Johannesburg, 2193

Tel: +27 11 611 1400 or +27 860 287 835

11. DATE OF PUBLICATION

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