Applicant/PHCR:	Ranbaxy Pharmaceuticals (Pty) Ltd
Product proprietary name:	BETAMOX 250, BETAMOX 500, BETAMOX S, BETAMOX SF
Dosage form and strength:	Capsules; 250 mg & 50 mg amoxycillin trihydrate

Patient Information Leaflet

SCHEDULING STATUS

S4

BETAMOX® 250 capsules

Sugar free

BETAMOX® 500 capsules

Sugar free

BETAMOX® S 125 mg/5 ml suspension

Contains sugar: Sucrose (Pharmagrade sugar) 3,031 g

BETAMOX® SF 250 mg/5 ml suspension

Contains sugar: Sucrose (Castor sugar) 2,873 g

Amoxycillin

Read all of this leaflet carefully before you start taking/giving BETAMOX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BETAMOX® 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.

What is in the leaflet

1. What BETAMOX® is and what it is used for

2. What you need to know before you take/give BETAMOX®
3. How to take/give BETAMOX®
4. Possible side effects
5. How to store BETAMOX®
6. Contents of the pack and other information

1. What BETAMOX® is and what it is used for

BETAMOX® (amoxycillin) belongs to a group of antibiotic medicines called penicillins. BETAMOX® works by interfering with the growth of the bacteria that causes the infection.

BETAMOX® is used to treat various infections caused by bacteria in different parts of the body.

2. What you need to know before you take BETAMOX®

Do not take/give BETAMOX®

- if you are allergic to penicillin (e.g. amoxycillin), or any other antibiotic or any of the other ingredients of BETAMOX® (listed in section 6).
- if have glandular fever (symptoms include fever, sore throat, swollen glands and extreme tiredness), as you will have an increased chance of getting a rash.
- if you have lymphatic leukaemia, a type of cancer of the blood and bone marrow.
- if you have high levels of uric acid in the blood and are taking allopurinol (a medicine used to treat gout), as you will have an increased chance of getting a rash.

Warnings and precautions

Special care should be taken with BETAMOX®:

- if you develop a rash, treatment with BETAMOX® may need to be stopped.

- if you suffer from seizures.
- if you have kidney problems (dosage adjustment is required).
- if you develop a secondary infection, tell your doctor.
- if you are using BETAMOX® for a prolonged period of time, your doctor may conduct kidney or liver function tests, or blood tests.
- if you are not urinating regularly.
- if you are having urine (glucose) tests or oestriol tests (used during pregnancy) as the results of these tests may be inaccurate.

Other medicines and BETAMOX®

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Probenecid (used for gout); your doctor may decide to adjust your dose of BETAMOX®.
- Allopurinol (used for gout); it may be more likely that you will have an allergic skin reaction.
- Medicines to help stop blood clots (such as warfarin); you may need extra blood tests.
- Other antibiotics (such as tetracycline) will result in BETAMOX® being less effective.
- Methotrexate (used for the treatment of cancer, rheumatoid arthritis and severe psoriasis); BETAMOX® may cause an increase in side effects.
- Oral contraceptives; BETAMOX® may decrease the efficacy of oestrogen-containing oral contraceptives.

BETAMOX® with food

BETAMOX® can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BETAMOX®.

Driving and using machines

BETAMOX® may cause an allergic reaction, dizziness or seizures. If you experience these side effects, do not drive or operate machinery.

BETAMOX® contains sugar

BETAMOX® suspension contains sucrose (sugar) which may have an effect on the control of your/your child's blood sugar if you/your child has diabetes mellitus. Sucrose may be harmful to the teeth. If you have been told by your doctor that you/your child has an intolerance to some sugars, contact your doctor before taking/giving BETAMOX® suspension.

3. HOW TO TAKE/GIVE BETAMOX®

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

Always take/give BETAMOX® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The average adult dose for BETAMOX® is 750 mg to 1,5 g per day.

General dosages

Adults: 250 mg (1 X 250 mg capsule or 5 ml of 250 mg/5 ml suspension) three times a day.

Children 2 to 10 years: 125 mg (5 ml of 125 mg/5 ml suspension) three times a day.
Children 6 months to 2 years: 125 mg (5 ml of 125 mg/5 ml suspension) three times a day.
Infants 0 to 6 months: 62,5 mg (2,5 ml of 125 mg/5 ml suspension) three times a day.

To reconstitute 75 ml suspension, add 44 ml of water, invert the bottle and shake well until all the powder is dispersed.
To reconstitute 100 ml suspension, add 57 ml of water, invert the bottle and shake well until all the powder is dispersed.

Your doctor will advise you on how much BETAMOX® to take/give depending on the severity and type of infection.

Your doctor will tell you how long your treatment with BETAMOX® will last. If you have the impression that the effect of BETAMOX® is too strong or too weak, tell your doctor or pharmacist.

If you take/give more BETAMOX® than you should

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

If you forget to take/give BETAMOX®

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking/giving BETAMOX®

Do not stop taking BETAMOX® without the advice of your doctor even if you feel better.

4. Possible side effects

BETAMOX® can have side effects.

Not all side effects reported for BETAMOX® are included in this leaflet. Should your/your child's general health worsen or if you/your chid experience any untoward effects while taking BETAMOX®, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fever, joint pain, swollen lymph nodes,
- blistering of the skin, peeling of the skin,
- fluid filled bumps under the skin,
- fainting.

These are all very serious side effects. If you/your child has them, you/your child may have had a serious reaction to BETAMOX®. You/your child 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:

- low number of white blood cells (leucopenia). Signs include: fever, chills, sore throat,
- low number of cells involved with blood clotting (thrombocytopenia). Signs include: more or worse bruises than normal, small purple or red dots under your skin, nosebleeds or bleeding gums, black or bloody-looking bowel movements, red or pink urine,
- an excessive breakdown of red blood cells causing a type of anaemia (haemolytic anaemia). Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes,
- the blood may take longer to clot than it normally would. You may notice this if you have a nosebleed or cut yourself,
- seizures,
- inflammation of the large bowel (colon) with diarrhoea (sometimes containing blood), pain and fever,
- liver problems. Signs include: severe diarrhoea and bleeding, darker urine or paler stools, yellowing of the skin or whites if the eyes (jaundice),
- kidney problems. Signs include: blood in the urine, fever, increased or decreased urine output, crystals in the urine which may be seen as cloudy urine, or difficulty or discomfort in passing urine.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea,
- nausea.

Less frequent side effects:

- thrush (a yeast infection of the vagina, mouth or skin folds),
- muscle spasm, hyperactivity and inability to concentrate,
- dizziness,
- vomiting,
- the tongue may change to yellow, brown or black and it may have a hairy appearance,
- discolouration of teeth.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of BETAMOX®.

5. How to store BETAMOX®

- Store all medicines out of reach of children.
- 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 below 25 °C.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label or bottle.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What BETAMOX® contains

The active substance is amoxycillin.

BETAMOX® 250

Each capsule contains amoxycillin trihydrate equivalent to 250 mg amoxycillin.

BETAMOX® 500

Each capsule contains amoxycillin trihydrate equivalent to 500 mg amoxycillin.

BETAMOX® S

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

BETAMOX® SF

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

The other ingredients are:

BETAMOX® 250 and BETAMOX® 500

Capsule contents:

Magnesium stearate, purified talc and sodium lauryl sulphate

Capsule shell:

Flesh opaque body: erythrosine (CI no. 45430), gelatin, quinoline yellow (CI no. 47005), titanium dioxide (CI no. 77891)

Maroon cap: brilliant blue (CI no. 42090), erythrosine (CI no. 45430), gelatin, sunset yellow (CI no. 15985), titanium dioxide (CI no. 77891)

Capsule printing ink:

Yellow printing ink: butyl alcohol, dehydrated alcohol, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution, yellow iron oxide (CI no. 77492)

Black printing ink: absolute alcohol, black iron oxide (CI no. 77499), butyl alcohol, isopropyl alcohol, propylene glycol, shellac

BETAMOX® S

Hexacol grape A B 100 concentration (grape colour): hexacol brilliant blue FCF supra (CI no. 42090) and hexacol carmoisine (red) (CI no. 14720), sodium acid citrate, sodium carboxymethyl cellulose, sodium citrate, sucrose (pharmagrade sugar), Trusil grape concord (F1526) (grape flavour)

BETAMOX® SF

Castor sugar (starch free), Hexacol grape A B 100 concentration (grape colour): hexacol brilliant blue FCF supra (CI no. 42090) and hexacol carmoisine (red) (CI no. 14720), sodium acid citrate, sodium carboxymethyl cellulose, sodium citrate, sucrose (pharmagrade sugar), Trusil grape concord (F1526) (grape flavour)

What BETAMOX® looks like and contents of the pack

BETAMOX® 250

Size 2 capsule, with an opaque maroon cap and an opaque flesh coloured body. The name BETAMOX 250 mg is imprinted on the flesh body, and the Be-Tabs logo on the maroon cap.

Canisters containing 15, 100 or 500 X 250 mg amoxycillin capsules.

Patient ready packs of different pack sizes.

BETAMOX® 500

Size 0 capsule, with an opaque maroon cap and an opaque flesh coloured body. The name BETAMOX 500 mg is imprinted on the flesh body, and the Be-Tabs logo on the maroon cap.

Canisters containing 15, 100 or 500 X 500 mg amoxycillin capsules.

Patient ready packs of different pack sizes.

BETAMOX® S

Free-flowing, slightly pink powder, purple suspension when reconstituted.

Bottles containing powder for reconstitution to 75 ml and to 100 ml of 125 mg / 5 ml suspension.

BETAMOX® SF

Free-flowing, slightly pink powder, purple suspension when reconstituted.

Bottles containing powder for reconstitution to 100 ml of 250 mg/5 ml suspension.

Holder of Certificate of Registration

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South Africa

This leaflet was last revised in

30 April 2021

Registration numbers

BETAMOX® 250

Y/20.1.2/127 (S.A.)

Botswana: S2 BOT0500765

Namibia: NS2 04/20.1.2/1625

BETAMOX® 500

Y/20.1.2/128 (S.A.)

Namibia: NS2 04/20.1.2/1626

BETAMOX® S

Y/20.1.2/129 (S.A.)

Botswana: S2 BOT0500763

Namibia: NS2 04/20.1.2/1623

BETAMOX® SF

Y/20.1.2/130 (S.A.)

Botswana: S2 BOT0500764

Namibia: NS2 04/20.1.2/1624

Access to the corresponding Professional Information

To follow