

BEAMOXY TABLET/CAPSULE/GRANULES

Amoxicillin (250mg, 500mg, 250mg/5ml, 125mg/5ml)

What is in the leaflet

1. What BEAMOXY is used for
2. How BEAMOXY works
3. Before you use BEAMOXY
4. How to use BEAMOXY
5. While you are using it
6. Side effects
7. Storage and Disposal of BEAMOXY
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What BEAMOXY is used for

Amoxicillin is an antibiotic used to treat infections in different parts of the body caused by bacteria. These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and soft tissues.

Your doctor may have prescribed BEAMOXY for another reason. Ask your doctor if you have any questions about why BEAMOXY has been prescribed for you.

How BEAMOXY works

Amoxicillin is an antibiotic that belongs to a group of medicines called penicillins. These antibiotics work by killing the bacteria that are causing your infection.

Before you use BEAMOXY

- When you must not take it

Do not take BEAMOXY if you have an allergy to:

- amoxicillin,
- other penicillins or cephalosporins
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue.

Do not use BEAMOXY if:

1. The packaging is torn or shows signs of tampering.
2. Do not use BEAMOXY after the expiry date printed on the bottle or box has passed.
3. If you are not sure whether you should start taking BEAMOXY contact your doctor or pharmacist

- Before you start to use it

Tell your doctor if you have had an allergic reaction to any antibiotics in the past.

Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have ever had any other health problems / medical conditions, including:

- liver problems
- kidney problems
- bleeding disorder
- stomach and intestinal disease
- glandular fever (mononucleosis)
- other medical problems
- Please kindly inform your doctor if you need to perform any urine or blood test.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking BEAMOXY.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and BEAMOXY may interfere with each other. You may

need different amounts of your medicines, or you may need to take different medicines e.g.

- probenecid and allopurinol, medicines used to treat gout
- the contraceptive pill (birth control pill).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use BEAMOXY

Follow all directions given to you by your doctor and pharmacist carefully. These directions may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

Your doctor will tell you how much you need to take each day and when to take it. This depends on your condition and whether or not you are taking any other medicines.

For the treatment of most infections, the usual adult dose is 250 to 500 mg every 8 hours. For children, the dose may vary depending on the child's weight.

- When to use it

Take each dose of BEAMOXY at about the same time each day. Taking each dose of BEAMOXY at the same time each day will have the best effect. It will also help you to remember when to take the medicine. It may be taken with or without food.

- How long to use it

Continue taking BEAMOXY until you finish the pack or as your doctor recommends.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much BEAMOXY tablet, capsule or granules.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Some of the symptoms of overdose include:

- Nausea
- Vomiting
- Diarrhoea

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking BEAMOXY.

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after BEAMOXY has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you become pregnant while you are taking BEAMOXY tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and

pharmacist that you are taking BEAMOXY.

- Things you must not do

Do not stop taking BEAMOXY because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Do not take BEAMOXY to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how BEAMOXY affects you.

BEAMOXY may cause tiredness or dizziness in some people. Make sure you know how you react to BEAMOXY before you drive a car or do anything else that may be dangerous if you are affected.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- diarrhoea, watery and severe diarrhoea (several loose bowel movements per day), which may also be bloody
- nausea
- vomiting
- headache
- oral thrush (white, furry sore tongue and mouth)

- vaginal thrush (sore and itchy vagina, vaginal discharge).
- liver disorder (yellow eye or skin)
- difficulty or pain on passing urine; decreased amount of urine
- signs of frequent infections such as fever, sore throat or mouth ulcers
- mental disturbances
- bleeding or bruising more easily than normal
- fits or seizures

If any of the following allergic reactions happen, stop taking Beamoxy and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- any type of skin rash, itching, blistering or peeling of the skin, hives
- swelling of the face, lips, mouth or throat which may cause
- wheezing, shortness of breath or difficulty breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of BEAMOXY

- Storage

Keep your medicine in its original packaging until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Keep your medicine in a place where the temperature will stay below 25°C. Protect from light. For granules preparation, after reconstitution, store between 2 to 8°C, and discard 7 days after reconstitution.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product Description

- *What it looks like*

i) BEAMOXY TABLET 250
- A capsule shape, scored, marked 'USP250' yellow tablet.

ii) BEAMOXY TABLET 500
- A capsule shape, scored, marked 'USP500' yellow tablet.

iii) BEAMOXY GRANULES 125
- An almost white powder when reconstituted forms a yellow, fruity flavoured, homogenous suspension.

iv) BEAMOXY GRANULES 250
- An almost white powder when reconstituted forms a yellow, fruity flavoured, homogenous suspension

v) BEAMOXY CAPSULE 250
- A size 2, maroon/yellow capsule with marking 'UPHA/BEAMOXY 250' capsule.

vi) BEAMOXY CAPSULE 500MG
- A size 0, maroon/yellow capsule with marking 'UPHA/BEAMOXY 500' capsule.

- **Ingredients**

Active ingredient:

- Amoxicillin

Inactive ingredients:

BEAMOXY TABLET 250

- Saccharin sodium
- Sodium starch glycolate
- Magnesium stearate
- Pineapple flavour
- Aluminium Lake quinoline yellow
- Kollidon 30
- Aerosil 200
- Microcrystalline cellulose(Ph102)

BEAMOXY TABLET 500

- Quinoline yellow
- Saccharin sodium
- Sodium starch glycolate

- Microcrystalline cellulose(102)
- Aerosil 200
- Pineapple
- Povidone
- Magnesium stearate

BEAMOXY GRANULES 125

- Orange flavour
- Sodium carboxymethylcellulose
- Pineapple
- Dextrose anhydrous
- Propylparaben
- Colour ariavit quinoline yellow
- Saccharin sodium
- Methylparaben
- Aerosil 200

BEAMOXY GRANULES 250

- Saccharin sodium
- Orange flavour
- Sodium carboxymethylcellulose
- Aerosil 200
- Methylparaben
- ariavit quinoline yellow
- Dextrose anhydrous
- Propylparaben
- Pineapple

BEAMOXY CAPSULE 250

- Sodium Starch Glycolate
- Magnesium stearate

BEAMOXY CAPSULE 500

- Sodium Starch Glycolate
- Magnesium stearate

- MAL number

i) BEAMOXY TABLET 250
MAL20020025AZ

ii) BEAMOXY TABLET 500
MAL19860468AZ

iii) BEAMOXY GRANULES 125
MAL19860018AZ

iv) BEAMOXY GRANULES 250
MAL19860019AZ

v) BEAMOXY CAPSULE 250
MAL19860017AZ

vi) BEAMOXY CAPSULE 500
MAL19950398AZ

Manufacturer

UPHA PHARMACEUTICAL MFG (M) SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Section 13, 43650 Bangi Industrial Estate, Selangor Darul Ehsan

Product Registration Holder

UPHA PHARMACEUTICAL MFG (M) SDN BHD (53667-M)
Lot 2&4, Jalan P/7, Section 13, 43650 Bangi Industrial Estate, Selangor Darul Ehsan

Date of Revision

17/11/2015

Serial Number:

BPFK(R4/1)110116/00007