

BETAMOX CAPSULE/GRANULE

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

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What BETAMOX 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:

- Skin and skin structure
- Respiratory
- Urinary and genital tract
- Gonorrhoea (venereal disease)
- Prevention for the infection of the heart

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

How BETAMOX 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 BETAMOX

- When you must not use it

Do not take BETAMOX 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 BETAMOX if:

- The packaging is torn or shows signs of tampering.
- Do not use BETAMOX after the expiry date printed on the bottle or box has passed.
- If you are not sure whether you should start taking BETAMOX 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:

- blood disorders such as leukaemia
- liver problems
- kidney problems
- glandular fever (mononucleosis)

- history of diarrhea associated with antibiotic used.

Amoxicillin paediatric drops and sugar free syrups contain sodium benzoate.

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 BETAMOX.

- 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 BETAMOX may interfere with each other. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to use BETAMOX

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

The dose varies from person to person. 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.

If you have kidney disease, your doctor might recommend a lower dose for you.

- When to use it

Take each dose of BETAMOX at about the same time each day.

Taking each dose of BETAMOX 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 BETAMOX 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 BETAMOX Tablet.

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 BETAMOX.

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 BETAMOX 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 BETAMOX tell your doctor immediately.

If you have to test your urine for sugar, make sure your doctor knows which type of test you use. BETAMOX may affect the results of some of these tests.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking BETAMOX.

- Things you must not do

Do not stop taking BETAMOX 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 BETAMOX 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 BETAMOX affects you.

BETAMOX may cause tiredness or dizziness in some people. Make sure you know how you react to BETAMOX 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
- Skin rash
- Itching
- Stomach ache
- Difficulty or pain on passing urine
- Hypersensitivity
- Dizziness or convulsions
- Hyperkinesia (excessive abnormal movements)

Amoxicillin may cause severe skin reactions. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

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 Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumer->Reporting->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

BETAMOX may cause severe allergy and serious skin reactions.

Stop using BETAMOX and seek medical assistance immediately if you experience any of the following:

- Symptoms: skin reddening, blisters, rash, fever, sore throat or eye irritation
- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes

Storage and Disposal of BETAMOX

- 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 30°C. Protect from light.

For granules preparation, after reconstitution, store between 2 to 8°C.

For granules preparation, to be used 7 days after mixing. To remove the bottle from aluminium pouch when ready to be used.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

- 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

BETAMOX CAPSULE 250MG

- A size 2, grey/yellow capsule with marking 'DUO 861'.

BETAMOX CAPSULE 500MG

- A size 0, grey/yellow capsule with marking 'DUO 861'.

BETAMOX GRANULE 125MG/5ML

- White granules, on reconstitution it forms a white syrup.

BETAMOX GRANULE 250MG/5ML

- White granules, on reconstitution it forms a white syrup.

- Ingredients

Active ingredient:

- Amoxicillin Trihydrate

Inactive ingredients:

BETAMOX CAPSULE 250MG

- Lactose
- Magnesium stearate

BETAMOX CAPSULE 500MG

- Lactose
- Magnesium stearate

BETAMOX GRANULE 125MG/5ML

- Polyvinylpyrrolidone
- Mint flavour
- Sodium citrate
- Sodium saccharin

- Strawberry flavour
- Sodium carboxymethylcellulose
- Silicon dioxide
- Sucrose

BETAMOX GRANULE
250MG/5ML

- Polyvinylpyrrolidone
- Mint flavour
- Sodium citrate
- Sodium saccharin
- Strawberry flavour
- Sodium carboxymethylcellulose
- Silicon dioxide
- Sucrose

- MAL number

BETAMOX CAPSULE
250MG
MAL19890329AZ

BETAMOX CAPSULE
500MG
MAL19890330AZ

BETAMOX GRANULE
125MG/5ML
MAL19890246AZ

BETAMOX GRANULE
250MG/5ML
MAL19890247AZ

Manufacturer

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Product Registration Holder

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

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