

BEATACYCLINE CAPSULE 250MG

Tetracycline Hydrochloride (250mg)

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What Beatacycline is used for

Beatacycline is used for the treatment of a wide range of infections caused by bacteria and fungal organisms. These include:

- Respiratory tract infections such as pneumonia, bronchitis or whooping cough
- Urinary tract infections
- Sexually transmitted diseases such as chlamydia, gonorrhoea or syphilis
- skin infections such as acne
- Infections of the eye such as conjunctivitis
- Rickettsial infections such as Q fever or tick fever
- Other infections including bacterial infection due to intake of contaminated animal-derived food, in contact with infected bird species or transmitted from animals to humans and acute severe diarrhea due to ingested food or water contaminated with bacteria.

How Beatacycline works

Beatacycline contains tetracycline, which belongs to a group of medicines called broad-spectrum antibiotic.

Bacteria could only cause infection if it is able to survive in the human body. Tetracycline works by interfering with the ability of bacteria to grow and multiply in human body. Hence, stopping the infection and the remaining bacteria would be killed by our immune system.

Before you use Beatacycline

- When you must not use it

1. Do not use Beatacycline after the expiry date printed on the pack.
2. Do not use Beatacycline if the packaging shows signs of tampering
3. Do not use Beatacycline to treat any other conditions unless advised by your doctor.
4. Do not use Beatacycline if you have history of hypersensitivity (allergy) to any tetracycline
5. Do not use Beatacycline if you have systemic lupus erythematosus (autoimmune disease that attacks one's own cell).
6. Do not use Beatacycline if you have severe kidney damage.
7. Do not use Beatacycline in children up to the age of 8 years as it may result in impaired bone growth and permanent discolouration of the child's teeth.

Pregnancy and lactation

Do not take Beatacycline if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Beatacycline if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Care should be taken when taking Tetracycline if you have impaired liver function. High doses should be avoided.

Alert to those who may be exposed to direct sunlight due to the risk of photosensitivity.

Beatacycline is not suitable for everyone. Be sure that your doctor knows about the following before you take Beatacycline:

1. If you are allergic to:

- Tetracycline
- other similar antibiotics (such as minocycline or doxycycline)
- Any other ingredient listed at the end of this leaflet.

2. If you suffer from:

- A kidney or liver problem or a long time, or severe kidney disease
- Suffer from myasthenia gravis, a condition characterized by muscle weakness, difficulty chewing and swallowing and slurred speech.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any other medication such as:

Especially:

- lithium (to treat bipolar disorder or depression)
- digoxin (to treat an uneven heartbeat, arrhythmia)
- theophylline (to treat asthma or other lung diseases)
- oral anticoagulants (to stop blood from clotting)
- ergot alkaloids (to treat migraine)
- methotrexate (used in rheumatoid arthritis)
- medicines which may damage your liver like erythromycin, chloramphenicol, isoniazid, and sulphonamide. (Check with your doctor or pharmacist to see if this applies to any medicines you are taking)
- methoxyflurane (an anesthetic), if you need an operation, tell your doctor or dentist you are taking tetracycline
- diuretics (water tablets such as furosemide)
- medicines containing aluminium, bismuth, calcium, iron, magnesium, zinc, choline and magnesium salicylate.

- antacids (to treat indigestion or heartburn), and sucralfate (to treat ulcers)
- colestipol or colestyramine (to lower cholesterol in body)
- oral contraceptive containing estrogen. Tetracycline capsule may make the oral contraceptive pill less effective. It is advisable that you should use additional contraceptive precautions while taking tetracycline.
- penicillins (antibiotic to treat infection)

Your doctor or pharmacist will have a complete list of the medicines that may cause problems when taken with Beatacycline.

How to use Beatacycline

- How much to use

For adults:

All infections due to Group A beta-haemolytic streptococci should be treated for at least 10 days.

For adults (including the elderly) and children over 12 years:

The minimum recommended dosage is 250mg every six hours.

Therapeutic levels are attained more rapidly by the administration of 500mg initially, followed by 250mg every six hours. For severe infections, the dosage may be increased to 500mg every six hours.

For Streptococcal infections: A therapeutic dose of tetracycline should be administered for at least 10 days.

For treatment of acne vulgaris and severe rosacea: 250-500mg daily in single or divided doses should be administered for at least three months.

For brucellosis: 500mg tetracycline four times daily accompanied by streptomycin.

For uncomplicated gonococcal infections (except anorectal infections in man):

500mg four times daily for 7 days

For primary and secondary syphilis: 500mg four times daily for 15 days.

For syphilis of more than one year's duration, (latentsyphilis of uncertain or more than one year's duration, cardiovascular or late benign syphilis) except neurosyphilis: 500mg, four times daily for 30 days

For acute epididymo-orchitis caused by Chlamydia trachomatis, or Neisseria gonorrhoea: 500mg four times daily for 10 days

For uncomplicated urethral, endocervical or rectal infection caused by Chlamydia trachomatis: 500mg four times daily for 7 days

For renal impairment: In general, tetracyclines are contraindicated in renal impairment and the dosing recommendations only apply if use of this class of drug is deemed absolutely essential. Total dosage should be decreased by reduction of recommended individual doses and/or by extending time intervals between doses.

For elderly

Usual adult dose.

For children under 12 years

Contraindicated in this age group.

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

Your doctor and pharmacist will be able to tell you:

- How many capsules to take at each dose.
- How many doses to take each day.
- When to take each of your doses.

If there is something that you do not understand ask either your doctor or pharmacist.

- When to use it

Use as directed by your doctor or pharmacist.

This dose may be varied by your doctor depending on your condition and the response of your body.

Your doctor may also vary the Beatacycline dosage for other medical reasons.

- How long to use it

Continue taking Beatacycline for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you have forgotten to take more than one dose, contact your doctor or pharmacist for advice.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department at the nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Drink plenty of fluids and take your medicine exactly as your doctor has told you.

Tetracycline should be taken one hour before or two hours after meals, since food and some dairy products interfere with absorption. The tablets should be taken with a good drink of water.

Your doctor or pharmacist will tell you whether there are any special instructions while you are taking Beatacycline.

See your doctor if you feel that your condition is not improving or getting worse.

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

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take this medicine within 1 to 3 hours of other medicines, milk or other dairy products.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Beatacycline to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the capsule makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Beatacycline can cause side effects, although not everybody gets them.

Tell your doctor if you notice any of the following symptoms and it worries you:

Common side effects:

- Gastrointestinal effects such as diarrhea, nausea and vomiting.
- Dry mouth, inflammation of tongue, mouth and lips, and difficulties in breathing.
- Central Nervous System (CNS) toxicity and photosensitivity.
- Discolouration of teeth and enamel hypoplasia (condition where the enamel of the teeth is hard but thin and deficit in amount).

- Interference of bone growth if given to infants or pregnant women.

Less common side effects:

- Oral candidiasis.
- Vulvovaginitis (inflammation of the vulvo and vaginal area).
- itchiness around the anus
- inflammation of the intestines
- Darkened or discolouration of the tongue.

Rare side effects

- Increased intracranial pressure (pressure within skull) and bulging fontanelles (spaces between bones of the skull) in infants.
- threatening allergic reaction
- Abnormal pigmentation of skin and eye, blood disorders such as reduced red blood cell, platelet, blood clotting factors and increase in white blood cell.
- Permanent discolouration of cornea in infants born from mothers that takes high doses for this medication during pregnancy.
- nearsightedness
- A Jarisch-Herxheimer-like reaction in individuals with relapsing fever (increased symptoms of relapsing fever)
- Severe and sometimes fatal hepatotoxicity which is associated with fatty changes in liver and pancreas (in pregnant woman or have kidney function impairment).

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

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 www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Beatacycline

- Storage

Keep Beatacycline in a cool dry place where the temperature stays below 30°C. Protect from light.

Keep your Beatacycline in the pack until it is time to take them. If you take the capsule out of the pack, they may not be kept well.

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

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

- Disposal

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Beatacycline Capsule 250mg: A size 2, plain, orange/yellow colour capsule

- Ingredients

- Active ingredient

Beatacycline Capsule 250mg: Each capsule contains 250mg of Tetracycline hydrochloride.

- Inactive ingredients

- Sodium Starch Glycolate
- Lactose Monohydrate
- Sodium Lauryl Sulphate
- Magnesium Stearate
- Talcum

- MAL number(s):

MAL19860247AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn Bhd.
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Product Registration Holder

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