

AA-MINOCYCLINE CAPSULE

Minocycline hydrochloride (50mg, 100mg)

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What AA-Minocycline is used for

AA-Minocycline is indicated for the treatment of various infections such as gallbladder, skin, soft tissues, urinary tract, respiratory tract and also as alternative medicine for sexually transmitted disease (gonorrhoea and syphilis).

How AA-Minocycline works

AA-Minocycline contains minocycline which is a tetracycline antibiotic that fights bacteria in the body. It acts by inhibiting protein production within the bacteria, thus preventing the growth and spread of bacteria.

Before you take AA-Minocycline

- When you must not take it

Do not take AA-Minocycline if you:

- are allergic to minocycline or to any of the other ingredients in AA-Minocycline (listed in Product Description)
- are allergic to other tetracycline antibiotics
- are pregnant or planning to become pregnant. Minocycline can cause damage to your unborn babies' bones and teeth. If you get pregnant

while taking Minocycline contact to your healthcare professional immediately.

- are breastfeeding or planning to breastfeed. Minocycline passes into human milk and can cause damage to your babies' bones and teeth. You should not breastfeed while taking Minocycline.
- have liver or kidney problems
- have the autoimmune disease myasthenia gravis
- are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Fructose intolerance
 - Sucrose-isomaltase insufficiency
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in Minocycline (listed in Product Description).

Minocycline is not recommended for children under 13 years old.

- Before you start to take it

Tell your doctor or pharmacist if you:

- have the autoimmune disease systemic lupus erythematosus
- suffer from allergies, asthma, hay fever or itchy skin rashes. You may be more likely to experience side effects while taking Minocycline.

Avoid exposure to direct sunlight and/or ultraviolet light while under treatment with minocycline or other tetracycline medicines. Treatment should be discontinued at the first evidence of skin redness or discomfort.

- Taking other medicines

Tell your doctor if you are taking:

- penicillin antibiotics, used to treat infections
- acne medicines known as retinoids
- quinapril, used to treat heart problems and high blood pressure
- blood thinners, used to prevent blood clots
- birth control pills, Minocycline may make your birth control pills less effective. Talk to your healthcare professional about using a back-up method of birth control, such as condoms, while you are taking Minocycline.
- diuretics or "water pills" used to treat high blood pressure
- medicines used to treat migraines called ergot alkaloids
- antacids containing aluminum calcium, magnesium, bismuth or iron containing products
- magnesium or zinc salts

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.

How to take AA-Minocycline

- How much to take

Your doctor may recommend lower than usual doses if you have liver or kidney impairment.

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.

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Adults

The usual oral dosage of AA-Minocycline is 100mg or 200mg initially, followed by 100mg every 12 hours. Alternatively, if more frequent doses are preferred, two or four 50mg doses may be given initially, followed by one 50mg dose every 6 hours.

Children 13 years of Age or Older

The usual dosage of AA-Minocycline is 4mg/kg initially followed by 2mg/kg every 12 hours.

- When to take it

Take as directed by your doctor or pharmacist.

- How long to take it

Therapy should be continued for 1 or 2 days beyond the time when characteristic symptoms or fever have subsided.

For treatment of syphilis, AA-Minocycline therapy should be administered over a period of 10 or 15 days.

Take AA-Minocycline for the duration as your doctor recommends.

- If you forget to take it

Consult your doctor or pharmacist on what you should do if you forget to take 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 take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your 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.

Taking too many capsules may cause dizziness, nausea, vomiting, abdominal pain, intestinal bleeding, low blood pressure, lethargy, coma.

While you are taking AA-Minocycline

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking AA-Minocycline.

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

Take AA-Minocycline only with a doctor's prescription.

Serious Side Effects

Serious side effects, in some cases causing death, have been seen in people taking Minocycline. If you have any of the following symptoms stop taking Minocycline and seek immediate medical help.

- Allergic reaction (hypersensitivity) with skin rashes: rash, skin redness, peeling skin, blisters on your nose, mouth, eyes or genitals, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever, swollen lymph nodes combined with any of the

following: liver problems (yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite), lung problems (flu-like symptoms, cough, shortness of breath), kidney problems (decreased urination, nausea, vomiting, swelling of extremities, fatigue), heart problems (chest pain, fast or irregular heartbeat, shortness of breath, swelling in the legs, ankles or feet, fatigue)

- Lupus-like syndrome: joint and muscle pain, fatigue, fever, swollen lymph nodes, inflammation around the lungs or heart that causes pain or discomfort
- Serum-sickness syndrome: fever, generally feeling unwell, hives, itching, rash, joint pain, swollen lymph nodes

- Things you must not do

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

Do not take any new medicines without consulting your doctor or pharmacist.

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

- Things to be careful of

Driving or using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel headaches, light-headedness, dizziness, ringing in the ears or spinning sensation, do not drive or use machines and contact your doctor immediately.

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Side effects

Like all medicines, AA-Minocycline can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

Side effects may include:

- light-headedness, dizziness, vertigo (feeling like you're spinning or losing your balance)
- headache
- loss of appetite, constipation
- nausea, vomiting, diarrhea
- indigestion
- trouble swallowing
- inflammation or sores in the mouth, lips and/or tongue
- joint swelling, pain and stiffness, aching muscles
- rash, itching
- cough
- sleepiness
- fever

Minocycline can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects

Rare

- Fainting
- Liver problems: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite
- Inflammation or ulcers of the food pipe (esophagus): trouble swallowing, pain when swallowing, sore throat, hoarse voice, heartburn,

chest pain that is worse with eating, nausea

- Kidney problems: decreased urination, nausea, vomiting, swelling of extremities, fatigue
- Unusual hair loss or thinning
- Increased sensitivity of the skin to sun
- Discolouration of the nails, skin, tongue, gums, lips or teeth
- Shortness of breath

Very rare

- Pseudomembranous colitis: watery, bloody diarrhea, mucus in the stool, abdominal cramps and pain, fever
- Angioedema: swelling of the face, eyes, lips, tongue, throat, arms or legs, trouble breathing or swallowing, hoarseness, itching, hives, rash on the hands, arms and feet, fever, abdominal cramps
- Allergic reaction (hypersensitivity) with skin rashes: rash, skin redness, peeling skin, blisters on your nose, mouth, eyes or genitals, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fever, swollen lymph nodes combined with any of the following: liver problems (yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite), lung problems (flu-like symptoms, cough, shortness of breath), kidney problems (decreased urination, nausea, vomiting, swelling of extremities, fatigue), heart problems (chest pain, fast or irregular heartbeat, shortness of breath, swelling in the legs, ankles or feet, fatigue)
- Thyroid problems: weight changes, fatigue, heart palpitations,

constipation, dry skin, joint or muscle pain

- Yeast infections:
 - Oral: creamy white bumps on the tongue, cheeks, gums or throat that bleed when scraped, pain, trouble swallowing, bad taste in the mouth
 - Genital and Anal: genital (vagina or penis) or anal itching, burning during intercourse or urination, pain, redness, swelling, discharge
- Bronchospasm: pain, tightness and a feeling of constriction in the chest and back, trouble breathing, wheezing, coughing, dizziness

Not known

- Hearing problems: buzzing, ringing or other persistent noise in ear, loss of hearing
- Tingling or numbness of the hands or feet
- Lupus-like syndrome: joint and muscle pain, fatigue, fever, swollen lymph nodes, inflammation around the lungs or heart that causes pain or discomfort
- High blood pressure in the brain: headache, blurred vision, nausea, vomiting, confusion
- Respiratory disorder;
 - Pneumonitis: flu-like symptoms, cough, shortness of breath, fever, chills, fatigue
- Nervous system disorder;
 - Seizures or fits
- Gastrointestinal disorder;
 - Inflammation of the pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting
- Immune system disorder;

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| <ul style="list-style-type: none"> - Serum-sickness syndrome: fever, generally feeling unwell, hives, itching, rash, joint pain, swollen lymph nodes • Blood disorder; <ul style="list-style-type: none"> - Hemolytic anemia: pale skin, yellow skin, eyes and mouth (jaundice), dark-coloured urine, fever, weakness, dizziness, confusion, reduced ability to exercise - Low levels of white blood cells: infection, fatigue, fever, aches, pain, flu-like symptoms - Low levels of blood platelets: bruising, bleeding, fatigue, weakness | <p>Keep out of the reach and sight of children.</p> <p><u>- Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.</p> <p>Product Description <u>- What it looks like</u> <u>AA-Minocycline Capsules 50mg :</u> Light orange hard-gelatin capsule. Imprinted APO 50. Yellow powder fill. Available in bottles of 100's.</p> | <p>Product Registration Holder Pharmaforte (M) Sdn Bhd 2, Jalan PJU 3/49 Sunway Damansara 47810 Petaling Jaya Selangor</p> <p>Date of revision 10/6/2025</p> <p>Serial Number NPRA(R2/1)250429/1471</p> |
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Stop taking AA-Minocycline and contact your doctor immediately if you experience any of the following:

- 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of AA-Minocycline

- Storage

Store AA-Minocycline in its original package. AA-Minocycline capsules should be stored below 30°C.

AA-Minocycline Capsules 100mg :
Light orange/purple hard-gelatin capsule. Imprinted APO 100. Yellow powder fill. Available in bottles of 100's.

- Ingredients

- Active ingredient(s)
Minocycline hydrochloride
- Inactive ingredients
Magnesium stearate; Croscarmellose sodium; Lactose Monohydrate; stearic acid; Talc

- MAL number:

AA-Minocycline Capsules 50mg :
MAL19984325ACRZ

AA-Minocycline Capsules 100mg :
MAL19984324ACRZ

Manufacturer

Apotex Inc.
50 Steinway Boulevard,
Etobicoke, Ontario,
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