

UNIMED'S AZITHRAL TABLET USP

Azithromycin (250mg, 500mg)

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What UNIMED'S AZITHRAL is used for

UNIMED'S AZITHRAL is used for the treatment of certain infections caused by bacteria that are sensitive to it, such as:

- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- ear infections
- skin and soft tissue infections, with exception of infected burn wounds e.g. infection of the tube that carries urine from the bladder (urethra) or the neck of the womb (cervix) caused by *Chlamydia trachomatis* (bacteria).

How UNIMED'S AZITHRAL works

UNIMED'S AZITHRAL contains *Azithromycin* which belongs to a group of medicines called macrolide antibiotics. *Azithromycin* treats infections by preventing bacteria from growing.

Before you use UNIMED'S AZITHRAL

- When you must not use it

Do not take UNIMED'S AZITHRAL if:

- you are allergic to Azithromycin dihydrate, erythromycin or any macrolide or ketolide antibiotic
- you are allergic to any of the other ingredients of this medicine (listed in section 6).

- Before you start use it

Talk with your doctor or pharmacist before taking UNIMED'S AZITHRAL if:

- you have severe liver or kidney problems
- you have severe heart problems or problems with your heart beat such as long QT syndrome (shown on an electro-cardiogram or ECG machine)
- your blood levels of potassium or magnesium are too low
- you develop signs of another infection
- you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with UNIMED'S AZITHRAL (see section "Taking other medicines")
- you have a certain type of muscle weakness called myasthenia gravis
- you have nervous (neurological) or mental (psychiatric) problems.

- Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

- antacids - used for heartburn and indigestion. UNIMED'S AZITHRAL should be taken at least 1 hour before or 2 hours after the antacid
- ergotamine - (used for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain)
- warfarin or similar medicines - used to thin the blood. UNIMED'S AZITHRAL can thin the blood even more
- digoxin- (used to treat heart problems) should not be taken at the

same time as this may cause raised digoxin levels in the body

- terfenadine - (used to treat hay fever) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine)
- zidovudine or nelfinavir - used to treat HIV infections. Taking nelfinavir with UNIMED'S AZITHRAL may mean that you get more of the side effects listed in this leaflet
- rifabutin - used to treat tuberculosis (TB)
- cyclosporin - used to stop your body rejecting an organ transplant. Your doctor will regularly check your blood levels of cyclosporin and may change your dose. Tell your doctor or pharmacist if you are taking any of the following medicines. UNIMED'S AZITHRAL can make the effects of these other medicines stronger. Your doctor may change your dose:
- theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD)

How to use UNIMED'S AZITHRAL

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For adults and young people with a body weight of 45kg or over

500mg once daily during three days with a total dose of 1500mg.

For infections of the neck of the womb and urethra caused by *Chlamydia trachomatis*

One dose of 1000mg, to be taken one time.

Children and adolescents under 45kg

The tablets are not recommended. Young people with a body weight of

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less than 45kg should use other forms of this medicine.

Patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

Dosage for elderly

For elderly the same dosage as for adults applies.

Administration

The tablets should be taken with ½ glass of water.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking UNIMED'S AZITHRAL for as long as your doctor recommends.

- If you forget to use it

If you forget to take UNIMED'S AZITHRAL, take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one when it is due. If in doubt, please contact your doctor or pharmacist. If you have to skip a dose, still take all of your tablets. This means that you will finish your course a day later.

Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you have taken too much UNIMED'S AZITHRAL, contact your doctor, pharmacist or go to your nearest hospital at once.

Symptoms of overdose are loss of hearing, feeling sick or being sick and diarrhoea. In case of overdosage

admission into hospital may be necessary.

While you are using it

- Things you must do

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is insufficient information available about the use of UNIMED'S AZITHRAL during pregnancy. Therefore you should not use UNIMED'S AZITHRAL during pregnancy, unless explicitly advised by your doctor. No data on secretion of azithromycin in breast milk are available. Therefore if you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

- 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.

Do not give UNIMED'S AZITHRAL to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

There are no data available about the influence of UNIMED'S AZITHRAL on the ability to drive or operate machines.

However UNIMED'S AZITHRAL tablets may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

UNIMED'S AZITHRAL contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects

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

If you have any of the following symptoms of a severe allergic reaction stop taking this medicine and tell your doctor immediately or go to the casualty department at your nearest hospital

- Sudden difficulty in breathing, speaking and swallowing
- Swelling of the lips, tongue, face and neck
- Extreme dizziness or collapse
- Severe or itchy skin rash, especially if this shows blistering and there is soreness of the eyes, mouth or genital organs.

If you experience any of the following side effects contact your doctor as soon as possible

- Diarrhoea that is serious, lasts a long time or has blood in it, with stomach pain or fever. This can be a sign of a serious bowel inflammation. This is something that can rarely happen after taking antibiotics
- Yellowing of the skin or whites of the eyes caused by liver problems
- Inflammation of the pancreas, which causes severe pain in the abdomen and back
- Increased or reduced urine output, or traces of blood in your urine
- Skin rash caused by sensitivity to sunlight
- Unusual bruising or bleeding
- Irregular heart beat.

These are all serious side effects. You may need urgent medical attention. Serious side effects are uncommon (may affect up to 1 in 100 people) or the frequency cannot be estimated from the available data.

Other side effects include

Very common (may affect more than 1 in 10 people)

- diarrhoea

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- abdominal pain
- feeling sick (nausea)
- loose wind (flatulence).

Common (may affect up to 1 in 10 people)

- lack of appetite (anorexia)
- feeling dizzy
- headache
- sensation of pins and needles or numbness (paraesthesia)
- changes in your sense of taste
- visual impairment
- deafness
- being sick (vomiting), stomach pain or cramps, loss of appetite, problems digesting your food
- skin rashes and itching
- joint pain (arthralgia)
- fatigue
- change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.

Uncommon (may affect up to 1 in 100 people)

- thrush (candidiasis) - a fungal infection
- fungal infection
- bacterial infection
- inflammation of the throat (pharyngitis)
- breathlessness, chest pain, wheeze and cough (respiratory disorder)
- inflammation of the mucous membrane inside the nose (rhinitis)
- stomach flu (gastroenteritis)
- inflammation inside your vagina (vaginitis)
- pneumonia
- reduction in the number of white blood cells
- angioedema
- hypersensitivity
- nervousness
- reduced sense of touch (hypoesthesia)
- feeling drowsy (somnolence)
- having difficulty sleeping (insomnia)
- ear disorder
- spinning sensation (vertigo)
- hearing loss or ringing in your ears
- palpitations
- hot flushes

- shortness of breath
- nosebleed
- inflammation of the lining of the stomach (gastritis)
- constipation
- difficulty swallowing
- swollen abdomen
- dry mouth
- belching
- mouth ulcer
- increased salivary flow
- liver problems such as hepatitis
- allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin
- severe form of skin flushing
- inflammation of the skin (dermatitis)
- dry skin
- increased sweating
- pain, swelling and reduced motion in your joints (osteoarthritis)
- muscle pain
- back pain
- neck pain
- increase in blood urea levels
- painful or difficult urination
- pain in the upper back (renal pain)
- spotting
- testicular disorder
- urticaria
- chest pain
- face swelling
- fever
- pain, numbness, muscle weakness, burning or tingling sensation (peripheral pain)
- swelling (oedema)
- general feeling of being unwell (malaise)
- weakness (asthenia)
- change in liver enzyme levels and blood levels
- post procedural complications

Rare (may affect up to 1 in 1,000 people)

- feeling agitated, feeling of unreality to the self and own feeling
- abnormal hepatic function
- allergic skin reactions
- swelling of the hands, feet, lips,

- genitals or throat (angioneurotic oedema)
- kidney problems.

Not known (frequency cannot be estimated from the available data)

- gut (colon) infection (pseudomembranous colitis)
- reduced number of red blood cells due to destruction (haemolytic anaemia); reduction in number of platelets (thrombocytopenia)
- anaphylactic reaction
- feeling angry, aggressive
- anxiety
- confusion
- hallucination
- fainting (syncope)
- fits (convulsions)
- feeling hyperactive
- change in your sense of smell (anosmia, parosmia)
- change in your sense of taste (ageusia)
- exacerbation or aggravation of muscle weakness (myasthenia gravis)
- rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm found by an electro-cardiogram (QT prolongation and torsade de pointes)
- low blood pressure
- inflammation of the pancreas (pancreatitis)
- your tongue and teeth changes colour
- liver failure
- allergic skin reactions.

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

Storage and Disposal of UNIMED'S AZITHRAL

- Storage

Keep this medicine out of the sight and reach of children.

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Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

PVC/Alu blister: Store below 30°C, protected from light. This medicinal product does not require any special storage conditions.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

UNIMED'S AZITHRAL TABLET USP 250mg: Round, biconvex, light yellow to yellow color film coated tablets plain on both sides.

UNIMED'S AZITHRAL TABLET USP 500mg: Capsule shaped, biconvex, light yellow to yellow color film coated tablets plain on both sides.

- Ingredients

- Active ingredient

Azithromycin dihydrate 250mg

Azithromycin dihydrate 500mg

- Inactive ingredients

Lactose, Croscarmellose Sodium, Colloidal Anhydrous Silica, Povidone, Magnesium Stearate, Talc, Maize starch(dried), Croscarmellose Sodium, Polacrillin Potassium, Hypromellose, Talc, Titanium Dioxide, Yellow Oxide of Iron, Macrogol 4000

- MAL number:

MAL08061570AZ (UNIMED'S AZITHRAL TABLET USP 250mg)

MAL08061571AZ (UNIMED'S AZITHRAL TABLET USP 500mg)

Manufacturer

Scott- Edil Pharmacia Ltd.
Unit II Plot No. 21-22, EPIP,
Phase 1, Jharmajri, Baddi,
Dist. Solan, HP - 173 205

Product Registration Holder

UNIMED SDN BHD
No.53 Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur

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