Azithromycin 500mg Film-coated Tablets

1. What Azithromycin is and what it is used for

Azithromycin belongs to a group of medicines called macrolide antibiotics. Antibiotics are used to treat infections caused by microorganisms like bacteria.

Azithromycin is used in the treatment of certain infections caused by bacteria that are sensitive to it, such as:
- ear infections
- chest, throat or nasal infections (such as bronchitis, pneumonia, tonsillitis, sore throat (pharyngitis) and sinusitis)
- skin and soft tissue infections, with exception of infected burn wounds e.g. - infection of the tissue that carves urine from the bladder (urethritis) or the neck of the womb (cervix) caused by Chlamydia trachomatis (bacteria)

2. What you need to know before you take Azithromycin

2.1 Do not take this medicine if:
• you are allergic to azithromycin dihydrate, erythromycin or any macrolide or ketolide antibiotics

2.2 Tell your doctor or pharmacist if you are taking, have recently taken or might take:
- cholesterol lowering medicines (statins)
- ergotamine - (used for migraine) as these medicines should not be taken together with azithromycin (see section “Taking other medicines”)
- other medicines:
  - quinidine - used to treat heart rhythm problems
  - rifabutin - used to treat tuberculosis (TB)
  - antacids - used for heartburn and indigestion. Azithromycin should not be taken with antacids because the effects of azithromycin (see section “Taking other medicines”) may change your dose. 

3. How to take Azithromycin

3.1 You should take your tablets:
- do not break or chew your tablets
- swallow your tablets with ½ glass of water

3.2 The tablets can be taken with or without food.

3.3 Dosage for elderly

- Patients with kidney or liver problems
- if you are allergic to azithromycin

3.4 If you forget to take Azithromycin

3.5 If you have taken too much Azithromycin

3.6 Driving and using machines

3.7 Breast-feeding

4. Possible side effects

4.1 The most common side effects of this medicine

4.2 If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. How to store Azithromycin

5.1 This medicine should be kept in the original packaging and stored:
- in a cool, dry place
- out of the reach of children

5.2 Do not store above 25°C

5.3 Do not use this medicine after the expiry date

6. What to do if you experience side effects

6.1 If you think you have experienced any side you should:

6.2 If you think you have experienced any side effects:

6.3 If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

7. Other medicines and Azithromycin

7.1 Medicines that may affect the use of azithromycin

8.azithromycin during pregnancy

8.1 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.

8.2 Children and adolescents under 14yrs

8.2.1 azithromycin is usually prescribed for children aged 4 to 12 years

8.3 azithromycin is not recommended. Young people with a body weight of less than 45kg should use other forms of this medicine.

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

8.5 Pregnancy, breast-feeding and fertility

8.5.1 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.

8.5.2 Azithromycin is partly passed through the mother's milk.

8.5.3 Azithromycin is not recommended for use during pregnancy.

8.5.4 There is insufficient information available about the use of azithromycin during pregnancy, therefore you should not use Azithromycin during pregnancy, unless explicitly advised by your doctor.

8.6 Driving and using machines

8.6.1 There are no data available about the influence of azithromycin on the ability to drive or operate machines. However azithromycin tablets may cause dizziness and drowsiness so make sure you are not affected before driving or operating machinery.

8.7 Azithromycin contains lactose

8.7.1 If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
**Azithromycin 500mg Film-coated Tablets PIL - UK**

- **Side effects**
  - Faintness (syncope)
  - hallucination
  - Feeling angry, aggressive
  - Anaphylactic reaction
  - Kidney problems.
  - Allergic skin reactions.
  - Feeling agitated, feeling of unreality to self and own feelings
  - Weakness (asthenia)
  - Swelling (oedema)
  - Fever
  - Face swelling
  - Chest pain
  - Urticaria
  - Neck pain
  - Pain, swelling and reduced motion in your joints (osteoarthritis)
  - Increased sweating
  - Inflammation of the skin (dermatitis)
  - Severe form of skin flushing
  - Mouth ulcer
  - Dry mouth
  - Swollen abdomen
  - Difficulty swallowing
  - Constipation
  - Inflammation of the lining of the stomach (gastritis)
  - Shortness of breath
  - Palpitations
  - Spinning sensation (vertigo)
  - Reduced sense of touch (hypoaesthesia)
  - Nervousness
  - Hypersensitivity
  - Reduction in the number of white blood cells
  - Stomach flu (gastroenteritis)
  - Inflammation of the mucous membrane inside the nose (rhinitis)
  - Breathlessness, chest pain, wheeze and cough (respiratory disorder)
  - Inflammation of the throat (pharyngitis)
  - Bacterial infection
  - Thrush (candidiasis) - a fungal infection
  - Change in the quantity of the white blood cells and the concentration of bicarbonate in the blood.
  - Uncommon (may affect up to 1 in 10 people)
    - Joint pain (arthralgia)
    - Skin rashes and itching
    - Headache
    - Severe form of skin flushing
    - Fever
    - Sore throat
  - Very common (may affect more than 1 in 10 people)
    - Loose stools.
  - Other side effects include
    - Fatigue
    - Nervousness
  - Rare (may affect up to 1 in 100 people)
    - Joint pain (arthralgia)
  - Other side effects include
    - Headache
    - Feeling dizzy
    - Swelling (oedema)
    - Feeling hyperactive
    - Change in your sense of smell (anosmia, parosmia)
    - Change in your sense of taste (geostasia)
    - Reduced or altered sensitivity or weakness (myasthenia gravis)
    - Rapid (ventricular tachycardia) or irregular heart beat, sometimes being life-threatening, changes of the heart rhythm (found by an electrocardiogram (ECG))
    - Low blood pressure
    - Inflammation of the pancreas (pancreatitis)
    - Your tooth and teeth change colour
    - Allergic skin reactions.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRa Yellow Card in the Google Play or Apple App Store.

**How to store Azithromycin**

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

**What Azithromycin looks like and contents of the pack**

- 6 film-coated tablets marked “500” on one side and plain on the other side.

**What Azithromycin contains**

- Azithromycin (as dihydrate).
- Macrogol and titanium dioxide (E171).
- Hydroxypropylcellulose, magnesium stearate (E464), hydroxypropylmethylcellulose, croscarmellose sodium (E403), mequinolin chloride (E572), methylcellulose (E463), polyvinylpyrrolidone (PVP K30), tartaric acid and sodium lactate.

**How to report suspected adverse reactions**

- If you suspect an adverse reaction, contact your doctor, pharmacist or nurse immediately. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRa Yellow Card in the Google Play or Apple App Store.

**Other information**

- The expiry date refers to the last day of that month.

**Packaging and storage**

- Film-coated tablets.

**Marketing Authorisation Holder and Manufacturer**

- Actavis, Barnstaple, EX32 8NS, UK
- Manufacturing Authorisation Holder and Manufacturer
- Actavis
- Actavis
- Iceland

**Further information**

- Further information may be obtained from the following source:
- Actavis
- Actavis
- Iceland