PACKAGE LEAFLET: INFORMATION FOR THE USER

Azithromycin Actavis 250 mg, film-coated tablets
Azithromycin Actavis 500 mg, film-coated tablets

Azithromycin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Azithromycin Actavis 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 micro-organisms like bacteria.

Azithromycin 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)

2. What you need to know before you take Azithromycin Actavis

Do not take Azithromycin Actavis 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).

Warnings and precautions
Talk with your doctor or pharmacist before taking Azithromycin Actavis 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 azithromycin (see section “Taking other medicines”)

- you have a certain type of muscle weakness called myasthenia gravis
- you have nervous (neurological) or mental (psychiatric) problems.

Other medicines and Azithromycin Actavis:
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. Azithromycin Actavis 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)
- cholesterol lowering medicines (statins)
- warfarin or similar medicines - used to thin the blood. Azithromycin Actavis can thin the blood even more.
- cisapride - (used to treat stomach problems) should not be taken at the same time as this may cause severe heart problems (shown on an electro-cardiogram or ECG machine).
- 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 Azithromycin Actavis may mean that you get more of the side effects listed in this leaflet.
- rifabutin - used to treat tuberculosis (TB)
- quinidine - used to treat heart rhythm problems
- 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. Azithromycin Actavis can make the effects of these other medicines stronger. Your doctor may change your dose:
- alfentanil - a painkiller used e.g. during operations
- theophylline - used for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD).
- digoxin - used to treat heart problems
- astemizol - used to treat hay fever
- pimozide - used to treat mental health problems

Azithromycin Actavis with food and drink
This medicine can be taken with or without food.

Pregnancy, breast-feeding and fertility
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 azithromycin during pregnancy. Therefore you should not use Azithromycin during pregnancy, unless explicitly advised by your doctor.

Azithromycin is partially passed through the mother’s milk, therefore Azithromycin should not be used if you are breast-feeding.

Driving and using machines
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 seizures so make sure you are not affected before driving or operating machinery.

Azithromycin Actavis 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.

3. How to take Azithromycin Actavis

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 45 kg or over:
500 mg once daily during three days with a total dose of 1500 mg. Your doctor may decide to prescribe the total dose of 1500 mg during a period of 5 days, with 500 mg the first day and 250 mg on days 2 to 5.

For infections of the neck of the womb and urethra caused by Chlamydia trachomatis:
One dose of 1000 mg, to be taken one time.

Children and adolescents under 45 kg:
The tablets are not recommended. Young people with a body weight of less than 45 kg 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

If you take more Azithromycin Actavis than you should
If you have taken too much Azithromycin Actavis, 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 stomach rinse and admission into hospital may be necessary.

If you forget to take Azithromycin Actavis
If you forget to take Azithromycin Actavis, 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 stop taking Azithromycin Actavis
Never stop the treatment with Azithromycin Actavis on your own, but first discuss this with your doctor. If the prescribed treatment is not completely finished, the infection may come back again.

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

4. Possible 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
- 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 infecion
- fungal infection
- bacterial infection
- inflammation of the throat (pharyngitis)
- breathlesness, chest pain, wheeze and cough (respiratory disorder)
- iflammation 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 (hypoaesthesia)
- 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
- hallucinations
- 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

The following side effects have been reported in prophylactic treatment against *Mycobacterium Avium* complex (MAC):

Very common (may affect more than 1 in 10 people)
- diarrhoea
- abdominal pain
- feeling sick (nausea)
- loose wind (flatulence)
- abdominal discomfort
- loose stools

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

Uncommon (may affect up to 1 in 100 people):
- reduced sense of touch (hypoaesthesia)
- hearing loss or ringing in your ears
- palpitations
- liver problems such as hepatitis
- severe form of skin flushing
- allergic skin reactions such as being sensitive to sunlight, red, flaking and swollen skin

- general feeling of being unwell (malaise)
- weakness (asthenia)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: + 353 1 6764971
Fax: + 353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie .

5. How to store Azithromycin Actavis

Keep this 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.

PVC/Alu blister: Store below 25°C. Store in the original packaging to protect from moisture.
OPA-PVC-Alu/Alu blister: This medicinal product does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Azithromycin Actavis contains

- The active substance is: Azithromycin dihydrate.
- Azithromycin Actavis 250 mg film-coated tablets contain 250 mg azithromycin (as dihydrate).
- Azithromycin Actavis 500 mg film-coated tablets contain 500 mg azithromycin (as dihydrate).
- The other ingredients are: Core: croscarmellose sodium (E468), magnesium stearate (E 572), microcrystalline cellulose (E460), silicium dioxide, (E551), poloxamer, povidone (E1201), talc, and waterfree lactose. Coating: hypromellose (E464), hydroxypropylcellulose, macrogol and titanium dioxide (E171).

What Azithromycin Actavis looks like and contents of the pack

Film-coated tablet.
Azithromycin Actavis 250 mg film-coated tablets are white to off-white oval, 6.7 x 13.5 mm, biconvex film-coated tablets marked "250" on one side and plain on the other side.

Azithromycin Actavis 500 mg film-coated tablets are white to off-white oval, 9.7 x 17.9 mm, biconvex film-coated tablets marked “500” on one side and plain on the other side.

250 mg tablets are available in a PVC/Alu and OPA-PVC-Alu/Alu blister of 4 and 6 film-coated tablets.
500 mg tablets are available in a PVC/Alu and OPA-PVC-Alu/Alu blister of 2 and 3 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

MA holder
Actavis Group PTC ehf.
Reykjavikurvegur 76-78
220 Hafnarfjörður
Iceland

Manufacturer
Actavis hf
Reykjavikurvegur 76-78
220 Hafnarfjörður
Iceland

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands	Azitrhomycine Actavis
Austria	Azithromycin Actavis 500 mg Filmtabletten
Bulgaria	Azatril
Czech Republic	Azithromycin Actavis 250 / 500 mg
Denmark	Azithromycin Actavis
Estonia	Azithromycin Actavis
Hungary	Zitinn 250 / 500 mg filmatbletta
Iceland	Azithromycin Actavis
Ireland	Azithromycin Actavis 250 / 500 mg Film-coated Tablets
Lithuania	Azithromycin Actavis 500 mg plėvele dengtos tabletės
Latvia	Azithromycin Actavis 500 mg apvalkotās tabletes
Malta	Actamycin
Poland	Azithromycin Actavis
Portugal	Azithromycin Sivatca
Romania	Azatril
Slovakia	Azithromycin Actavis 250 / 500 mg
Sweden	Azithromycin Actavis
United Kingdom	Azithromycin Actavis 250 / 500 mg film-coated tablets PL 30306/0387-0388

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