

Azithromycin Clonmel 250mg 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

- What Azithromycin Clonmel is and what it is used for
- What you need to know before you take Azithromycin Clonmel
- How to take Azithromycin Clonmel
- Possible side effects
- How to store Azithromycin Clonmel
- Contents of the pack and other information

1. What Azithromycin Clonmel is and what it is used for

Azithromycin is an antibiotic derived from erythromycin and belonging to a class named macrolide antibiotics. It acts by inhibiting the production of bacterial proteins, thus preventing bacteria from growing.

Azithromycin Clonmel is used to treat bacterial infections caused by microorganisms sensitive to azithromycin, such as:

- infections of the upper respiratory tract:
 - inflammation of the cavities of the nose (sinusitis)
 - inflammation of the throat (pharyngitis)
 - inflammation of the tonsils (tonsillitis)
- infections of the lower respiratory tract:
 - acute bacterial inflammation of the airways (acute worsening of a chronic bronchitis which is caused by a certain kind of bacteria)
 - mild to moderately severe community-acquired pneumonia (infection of the lungs which was not acquired in a hospital)
- acute middle ear infection (otitis media)
- skin and soft tissue infections
- uncomplicated inflammation of the urethra (urethritis) or the neck of the uterus (cervicitis) caused by a bacterium called *Chlamydia trachomatis*.

Your doctor has prescribed you Azithromycin Clonmel for the short-term treatment of your bacterial infection. Please note that there is no experience regarding the safety and efficacy of the long-term use of azithromycin. If your infection recurs quickly or constantly, your doctor may prescribe you another antibiotic.

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

DO NOT take Azithromycin Clonmel

- if you are allergic to azithromycin, to other macrolide antibiotics (e.g. erythromycin, clarithromycin, roxithromycin) or to any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Azithromycin Clonmel.

Please tell your doctor if you have or have had any medical conditions or illnesses, especially any of the following:

- **allergic (hypersensitivity) reactions:** Serious allergic reactions have been rarely reported, including angioedema and anaphylaxis. These conditions are life-threatening and require emergency care. Symptoms may include skin redness, hives, swelling of the lips, tongue or throat (angioedema). If you experience any of these symptoms, contact your local emergency medical services provider immediately. These reactions may recur and require a longer period of observation and treatment.
- **superinfection:** As with any antibiotic, treatment with azithromycin might lead to another infection caused by microorganisms (bacteria or fungi) that are or have become resistant to azithromycin. Please be aware of any signs of inflammation and infection.
- **Clostridium difficile associated diarrhoea (CDAD)**
This condition has been reported with the use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhoea to severe inflammation of the large intestine causing colitis e.g. abdominal pain, loss of appetite, cramping, fever.
- **pseudomembranous colitis** (bacterial infection of the large intestine): This condition has been reported in patients taking macrolide antibiotics. It is characterised by diarrhoea, fever and abdominal pain. You should not take any medicine that reduces bowel movements if you develop this condition.
- **disorders of heart's rhythm and electrical conduction**, such as innate or acquired prolongation of the QT interval (which causes irregular heart beat), bradycardia (lower heart rate), arrhythmia (irregular heart beat) or severe heart disease.
- **electrolyte disturbance** (change in the levels of the chemicals in the blood), particularly low level of potassium or magnesium.
- **infections caused by bacteria called *Streptococcus pyogenes*:** Inflammation of the throat or tonsils and rheumatic fever caused by this bacterium should be treated with penicillin.
- **infections caused by bacteria called *Treponema pallidum*** (e.g. syphilis).
- **severe kidney impairment**
- **liver problems:** your doctor may need to monitor your liver function or stop the treatment.
- **neurological or psychiatric disorders**
- **worsening and new onset of myasthenia gravis** (muscle disease where muscles become progressively weaker) has been reported.
- **infected burn wounds**
- **severe infections** which require a high concentration of the antibiotic in the blood quickly.

Other medicines and Azithromycin Clonmel

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

You should **NOT** take Azithromycin Clonmel together with any of the following medicines:

- **ergoline-based drugs** (e.g. ergotamine used to treat migraine; cabergoline and pergolide used to treat Parkinson's disease) – due to the risk of ergot poisoning (St. Anthony's fire).
- **medicines that prolong the QT interval**, such as drugs used to treat irregular heart beat (antiarrhythmics) of the class IA (sodium channel blockers, e.g. quinidine, procainamide and disopyramide) and class III (potassium channel blockers, e.g. amiodarone, dofetilide, sotalol, ibutilide), cisapride (used to treat gastric reflux disease and constipation) and terfenadine (used to treat allergic reactions) and antipsychotics (e.g. pimozide), antidepressants (e.g. citalopram) and certain other antibiotics that belong to a group called fluoroquinolones (e.g. moxifloxacin and levofloxacin) – due to the risk of developing irregular heart beat that can be life threatening.

Azithromycin may interact with the following medicines:

- **theophylline** (used to treat lung diseases such as chronic obstructive pulmonary disease and

asthma)

- **anticoagulants** (blood thinners) tablets of the coumarin-type (e.g. warfarin)
- **ciclosporin** (used to prevent rejection of a transplanted organ)
- **digoxin** (used for treatment of cardiac impairment)
- **colchicine** (used for gout and familial Mediterranean fever)
- **antacids** (stomach acid neutralisers): You should take azithromycin at least 1 hour before or 2 hours after the antacid.
- **fluconazole** (used to treat fungal infections)
- **zidovudine**, also called azidothymidine/AZT and nelfinavir (used to treat AIDS)
- **rifabutin** (antibiotic used to treat tuberculosis)
- **astemizole** (antihistamine/anti-allergic medicine used to treat e.g. runny nose, itching, watering of the eyes and other allergic symptoms).
- **alfentanil** (an analgesic drug)
- **statins, e.g. atorvastatin** (used for lowering blood cholesterol)
- medicines known to affect the rhythm of your heart such as **hydroxychloroquine** (used to treat rheumatoid arthritis and lupus, and to prevent and treat malaria)

Azithromycin Clonmel with food and drink

You may take Azithromycin Clonmel with food.

Pregnancy and breast-feeding

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.

Pregnancy

The safety of azithromycin during pregnancy has not been yet confirmed. Therefore, your doctor may prescribe you azithromycin only in life-threatening cases during pregnancy.

Breast-feeding

Azithromycin reaches your baby through the mother's milk, therefore, you should not breast-feed while you are taking azithromycin. You should discard the breast milk during the treatment. Thereafter, you may resume breast-feeding.

Driving and using machines

Azithromycin can cause side effects which can impair your ability to drive or use machines (e.g. dizziness and seizures). If you are prone to experience these types of side effects, you should not drive or use machines.

Azithromycin Clonmel contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Azithromycin Clonmel

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

Adults and elderly

You should take 500 mg azithromycin per day for three consecutive days (yielding a total dose of 1500 mg). Alternatively, you may take the same total dose (1500 mg) over five days. In this case, you should take 500 mg on day 1 and 250 mg on days 2 to 5.

If you have an inflammation of the urethra or the neck of the uterus caused by *Chlamydia trachomatis*, you should take 1000 mg azithromycin as a single dose.

Use in children

Children weighing more than 45 kg may take Azithromycin Clonmel in the same dose as adults. For children weighing less than 45 kg other medicine forms (e.g. suspensions) should be used.

Patients with impaired kidney function

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

If your kidney function is mildly to moderately impaired (GFR 10–80 ml/min), you may take the normal adult dose. If you suffer from a severe kidney impairment (GFR < 10 ml/min), a dose reduction may be necessary. Ask your doctor for advice.

Patients with impaired liver function

You should tell your doctor if you have liver problems as your doctor may need to alter the normal dose. Patients with mild to moderate liver impairment may take the normal adult dose. If you suffer from a severe liver disease, you should not take azithromycin. If this condition appears, you should stop treatment with azithromycin. Ask your doctor for advice.

Method of administration

Take your tablet(s) as a single daily dose with or without food.

Duration of treatment

Do not stop taking Azithromycin Clonmel unless your doctor tells you so.

If you take more Azithromycin Clonmel than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital casualty department immediately for advice. The symptoms of overdose include: reversible hearing loss, feeling sick, vomiting and diarrhoea.

If you forget to take Azithromycin Clonmel

If you miss a dose, take the tablet as soon as you remember. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Azithromycin Clonmel

Do not stop taking Azithromycin Clonmel without first talking to your doctor.

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. The following side effects have been reported:

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

- feeling sick (nausea)
- diarrhoea
- loose stools
- abdominal discomfort (pain and cramps)
- wind (flatulence)

Common (may affect up to 1 in 10 people):

- loss of appetite (anorexia)
- dizziness
- headache
- feeling of pins and needles (paraesthesia)
- disturbances of taste (dysgeusia)
- visual impairment

- deafness
- vomiting
- indigestion (dyspepsia)
- rash
- itching (pruritus)
- joint pain (arthralgia)
- tiredness (fatigue)
- altered numbers of white blood cells (lymphocytes, eosinophiles, basophils, monocytes and neutrophils) and blood bicarbonate decreased

Uncommon (may affect up to 1 in 100 people):

- infection with the fungus *Candida* (candidiasis) including fungus infection of the mouth
- infections caused by bacteria and fungi
- inflammation of the vagina (vaginitis)
- inflammation of the lungs (pneumonia)
- sore throat (pharyngitis)
- inflammation of the lining of the stomach and the intestines (symptoms may include nausea, vomiting, diarrhoea, and abdominal cramps)
- breathing disorder (respiratory disorder)
- swelling and irritation inside the nose (rhinitis)
- decreased number of white blood cells (leukopenia, neutropenia)
- increase in certain white blood cells (eosinophilia)
- serious allergic reaction which causes swelling of the lips, tongue or throat (angioedema)
- allergic reactions (hypersensitivity)
- feeling nervous
- reduced sense of touch (hypoaesthesia)
- sleepiness (somnolence)
- sleeplessness (insomnia)
- impaired hearing and/or tinnitus
- a feeling of dizziness or spinning (vertigo)
- earache (ear discomfort)
- feeling the heart beats (palpitations)
- inflammation of the stomach (gastritis)
- constipation
- difficulty swallowing (dysphagia)
- bloated abdomen with symptoms of feeling uncomfortably full and the presence of rumbling sounds in the stomach (abdominal distension)
- dry mouth
- mouth ulcers
- belching (eructation)
- increase of saliva (salivary hypersecretion)
- inflammation of the liver (hepatitis)
- Stevens-Johnson syndrome (a severe skin disorder with rash, blisters, red splotches and wounds)
- increased sensitivity to sunlight (photosensitivity)
- hives (urticaria)
- eczema or inflammation of the skin (dermatitis)
- dry skin
- increased sweating (hyperhidrosis)
- swelling of the face (face oedema)
- swelling of the ankles, feet or fingers (peripheral oedema)
- pain
- fever
- chest pain
- degenerative joint disease accompanied by pain and stiffness (osteoarthritis)

- muscle pain (myalgia)
- back pain
- neck pain
- accumulation of fluid in the body (oedema)
- pain passing urine (dysuria)
- low back pain (kidney pain)
- feeling ill (malaise)
- general weakness (asthenia)
- hot flushes
- difficulty breathing or painful breathing (dyspnoea)
- nosebleed (epistaxis)
- intermenstrual vaginal bleed (metrorrhagia)
- problems with the testes (testicular disorder)
- blood parameter changes (tell your doctor if you have a blood test)
- post procedural complication

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

- serious skin reactions: skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid)
- restlessness (agitation)
- abnormal liver function
- blockage of the flow of bile from the liver to the gut which causes yellowing of the skin and the whites of the eyes (cholestatic jaundice)

Very rare (may affect up to 1 in 10,000 people)

- Skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps.

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

- pseudomembranous colitis (bacterial infection of the large intestine)
- low number of blood platelets (thrombocytopenia)
- anaemia caused by an abnormal breakdown of red blood cells (haemolytic anaemia)
- severe life-threatening allergic reactions (anaphylaxis), including swelling of mouth and throat (oedema) – rarely life-threatening
- aggressive reactions
- anxiety
- severe confusion (delirium)
- seeing, hearing or feeling things that are not there (hallucinations)
- fainting (syncope)
- seizures (convulsions)
- feeling hyperactive
- problems/inability to smell (parosmia, anosmia)
- loss of taste (ageusia)
- worsening and new onset of **myasthenia gravis** (muscle disease where muscles become progressively weaker)
- irregular heart beat (arrhythmia), including fast heart beat (ventricular tachycardia)
- increased risk of QT prolongation (which causes irregular heart beat) and torsades de pointes (life-threatening fast heart beat)
- abnormal ECG heart tracing (electrocardiogram QT prolonged)
- low blood pressure (hypotension)
- inflammation of the pancreas (pancreatitis)
- discolouration of the tongue
- inflammation of the liver (hepatitis)
- death of liver cells and liver failure, which rarely was life-threatening

- toxic epidermal necrolysis (a very serious skin disorder characterised by peeling of the skin)
- erythema multiforme (a skin condition with itchy pink-red blotches)
- inflammation of the kidneys (interstitial nephritis)
- acute kidney failure

Azithromycin Clonmel film-coated tablets contain soya lecithin, which can very rarely cause allergic reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azithromycin Clonmel

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

This medicinal product does not require any special storage conditions.

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

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 Clonmel contains

The active substance is azithromycin.

Each Azithromycin Clonmel 250 mg film-coated tablet contains azithromycin dihydrate equivalent to 250 mg azithromycin.

The other ingredients are:

Tablet core:

- cellulose, microcrystalline
- starch, pregelatinised
- sodium starch glycolate
- silica, colloidal anhydrous
- sodium laurilsulfate
- magnesium stearate

Film coat:

- hypromellose
- lactose monohydrate
- titanium dioxide (E171)
- macrogol 4000

What Azithromycin Clonmel looks like and contents of the pack

Azithromycin Clonmel 250 mg film-coated tablets: white to off-white, oblong, film-coated, plain on both sides.

Azithromycin Clonmel is available in PVC/PVdC/Alu blisters.

Pack sizes: 4, 6, 12, 24, 50 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:

Clonmel Healthcare Ltd, Clonmel, Ireland

Manufacturer:

Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria

Sandoz S.R.L., 7A Livezeni Street, 540472 Targu Mures, Romania

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Germany	Azithromycin STADA 250 mg Filmtabletten
Luxembourg	Azithromycine EG 250, omhulde tabletten
Ireland	Azithromycin Clonmel 250 mg film-coated tablets
The Netherlands	Azitromycine CF 250 mg, filmomhulde tabletten
Finland	Azithromycin STADA 250 mg tabletti, kalvopäällysteinen

This leaflet was last revised in June 2022.