Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Azithromycin Capsules Abbreviated Prescribing Information. **Presentation:** Each capsule contains 250mg azithromycin (as dihydrate). **Indications:** For the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms: bronchitis, community-acquired pneumonia, sinusitis, pharyngitis/tonsillitis, otitis media, skin and soft tissue infections and uncomplicated genital infections due to *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. **Dosage and administration:** Azithromycin 250mg capsules are only suitable for children at least 45kg in body weight. *Adults, Elderly and Children (over 45kg body weight)*: 1500mg spread over three days (500mg once daily). In uncomplicated genital infections due to *C. trachomatis*, the dosage is 1000mg as a single oral dose. For susceptible *N. gonorrhoeae* the recommended dose is 1000mg or 2000mg of azithromycin in combination with 250mg or 500mg ceftriaxone according to local clinical treatment guidelines. *Renal impairment:* Dose adjustment not necessary in patients with slightly impaired renal function (GFR 10-80ml/min). Exercise caution in patients with a GFR of <10ml/min. *Hepatic impairment:* Should not be given to patients suffering from severe liver diseases. **Contraindications:** Hypersensitivity to the active substance, erythromycin, any macrolide or ketolide antibiotic or to any of the excipients. **Precautions and warnings:** Serious allergic reactions, including angioneurotic oedema and anaphylaxis (rarely fatal), dermatologic reactions including acute generalised exanthematous pustulosis (AGEP), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) (rarely fatal) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Reappearance of allergic symptoms may occur when symptomatic therapy is discontinued. As with any antibacterial agent, there is a possibility that superinfections could occur (e.g. fungal infections). The use of azithromycin should be undertaken with caution in patients with significant hepatic disease. Cases of fulminant hepatitis potentially leading to life-threatening liver failure have been reported with azithromycin. In case of signs and symptoms of liver dysfunction, liver function tests/ investigations should be performed immediately. Azithromycin administration should be stopped if liver dysfunction has emerged. Infantile hypertrophic pyloric stenosis (IHPS) has been reported following the use of azithromycin in neonates (treatment up to 42 days of life). Parents and caregivers should contact their physician if vomiting or irritability with feeding occurs. Ergotism has been precipitated by co-administration of some macrolide antibiotics. Due to the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administered. As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi, is recommended. *Clostridium difficile* associated diarrhoea (CDAD) has been reported with the use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild diarrhoea to fatal colitis. CDAD has been reported to occur over two months after the administration of antibacterial agents. Caution is advised in patients with severe renal impairment (GFR<10 ml/min) as this may result in increased systemic exposure of azithromycin. Prolonged cardiac repolarisation and QT interval, imparting a risk of developing cardiac arrhythmia and Torsades de Pointes, have been seen in treatment with other macrolides including azithromycin. A similar effect with azithromycin cannot be completely ruled out in patients at an increased risk for prolonged cardiac repolarization. **Interactions:** Azithromycin should be taken at least 1 hour before or 2 hours after an antacid if they are to be taken concomitantly. Concomitant administration of macrolide antibiotics with P-glycoprotein substrates (e.g. digoxin and colchicine), has been reported to increase serum levels of the P-glycoprotein substrate. Clinical monitoring, and possibly serum digoxin levels, during treatment with azithromycin and after its discontinuation are necessary. Azithromycin may increase the concentrations of phosphorylated zidovudine, the clinically active metabolite of zidovudine, in peripheral blood mononuclear cells. Post-marketing reports have been received of potentiated anticoagulation following co-administration of azithromycin and coumarin-type oral anticoagulants. Exercise caution before considering co-administering ciclosporin and azithromycin. If co-administration is necessary, carefully monitor ciclosporin levels and adjust the dose accordingly. Co-administration of azithromycin and nelfinavir may result in increased azithromycin concentrations. Neutropenia was observed in subjects receiving concomitant treatment of azithromycin and rifabutin. Co-administration of azithromycin is not known to have a significant impact on the pharmacokinetics of the following (see SmPC for more information): Cetirizine, didanosine (dideoxyinosine), atorvastatin, carbamazepine, cimetidine, efavirenz, fluconazole, indinavir, methylprednisolone, midazolam, sildenafil, terfenadine, theophylline, triazolam and trimethoprim/sulfamethoxazole. Azithromycin should be used with caution in patients receiving medicines known to prolong the QT interval with potential to induce cardiac arrhythmia (e.g. hydroxychloroquine). **Pregnancy and lactation:** There is limited epidemiological evidence of an increased risk of miscarriage following azithromycin exposure in early pregnancy. Therefore, azithromycin should only be used

during pregnancy if clinically needed, if adequate alternatives are not available, and if the benefit of treatment is expected to outweigh any small increased risks which may exist. Should not be used in the treatment of a lactating woman unless the physician feels that the potential benefits justify the potential risks to the infant. **Effects on ability to drive and use machines:** No evidence to suggest that azithromycin may have an effect on a patient's ability to drive or operate machinery. **Adverse reactions:** Pseudomembranous colitis, leukopenia, neutropenia, thrombocytopenia, haemolytic anaemia, angioedema, hypersensitivity reaction, anaphylactic reaction, syncope, myasthenia gravis, deafness, Torsades de Pointes, arrhythmia, ventricular tachycardia, gastritis, pancreatitis, hepatitis, hepatic failure, fulminant hepatitis, hepatic necrosis, cholestatic jaundice, Stevens-Johnson syndrome, AGEP, toxic epidermal necrolysis, erythema multiforme, DRESS and electrocardiogram QT prolongation. *Very Common***:** Diarrhoea, abdominal pain, nausea and flatulence. *Common:* Anorexia, dizziness, headache, paraesthesia, dysgeusia, visual impairment, vomiting, dyspepsia, rash, pruritus, arthralgia, fatigue, lymphocyte count decreased, eosinophil count increased and blood bicarbonate decreased. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. In cases of overdose, administration of medicinal charcoal and general symptomatic treatment as well as measures to support vital functions are indicated where necessary. **List Price:** Azithromycin 250mg Capsules Pack of 4: £3.58; Azithromycin 250mg Capsules Pack of 6: £2.61. **Legal category:** POM. **Marketing Authorisation Number:** PL 00289/1570. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00433. **Date of Preparation:** April 2025.