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 Film-Coated Tablets and Powder for Oral Suspension Abbreviated Prescribing Information. **Presentation:** Each film-coated tablet contains 250mg and 500mg azithromycin (as dihydrate). 5ml of reconstituted oral suspension contains 200mg azithromycin (as dihydrate). Each ml of reconstituted oral suspension contains 40mg azithromycin (as dihydrate). **Indications:** For the following bacterial infections induced by microorganisms susceptible to azithromycin: Infections of the lower respiratory tract (acute bronchitis and mild to moderate community-acquired pneumonia); Infections of the upper respiratory tract (sinusitis and pharyngitis/tonsillitis); Acute otitis media; Infections of the skin and soft tissue of mild to moderate severity (e.g. folliculitis, cellulitis, erysipelas); Uncomplicated *Chlamydia trachomatis* urethritis and cervicitis. **Dosage and administration:** *Adults, Elderly and Children (over 45kg body weight)*: 1500mg spread over three days (500 mg once daily) or spread over five days (500mg as a single dose on the first day and thereafter 250mg once daily). In uncomplicated *C. trachomatis* urethritis and cervicitis the dosage is 1000mg as a single oral dose. For sinusitis, treatment is aimed at adults and adolescents over 16 years of age. *Children (under 45kg body weight)*: Film-coated tablets not suitable for use in this patient population. Azithromycin suspension should be used in this patient population based on body weight. See SmPC for separate dosage recommendations. *Renal impairment:* Dose adjustment not necessary in patients with mild to moderate renal impairment (GFR 10-80ml/min). *Hepatic impairment:* Dose adjustment not necessary for patients with mild to moderately impaired liver function (Child-Pugh class A or B). **Contraindications:** Hypersensitivity to the active substance, erythromycin, any macrolide or ketolide antibiotic or to any of the excipients. **Precautions and warnings: S**erious allergic reactions, including angioedema and anaphylaxis (rarely fatal), drug reaction with eosinophilia and systemic symptoms (DRESS) and severe dermatologic reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson-syndrome and toxic epidermal necrolysis (TEN) 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. Caution is advised in patients with severe renal impairment (GFR<10 ml/min) as this may result in increased systemic exposure of azithromycin. Exercise caution in patients with significant hepatic disease. Cases of fulminant hepatitis potentially leading to life-threatening liver failure have been reported. Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur. 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. 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. 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. Azithromycin should be used with caution in patients with ongoing pro-arrhythmic conditions. Azithromycin is not suitable for treatment of severe infections where a high concentration of the antibiotic in the blood is rapidly needed. High resistance rates of *Streptococcus pneumoniae* (>30%) have been reported for azithromycin in some European countries. This should be taken into account when treating infections caused by *S. pneumoniae*. The main causative agent of soft tissue infections, *Staphylococcus aureus*, is frequently resistant to azithromycin. Susceptibility testing is considered a precondition for treatment of soft tissue infections with azithromycin. Azithromycin is not the substance of first choice for the treatment of pharyngitis and tonsillitis caused by *Streptococcus pyogenes*. Azithromycin is not often the substance of first choice for the treatment of sinusitis and acute otitis media. Azithromycin is not indicated for the treatment of infected burn wounds. In case of sexually transmitted diseases a concomitant infection by *Treponema pallidum* should be excluded. Observation for signs of superinfection with non-susceptible organisms, including fungi is recommended. Azithromycin should be administered with caution to patients suffering from neurological or psychiatric diseases. Azithromycin may exacerbate symptoms of myasthenia gravis and new onset of myasthenia syndrome. *Clostridioides 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. Pseudomembranous colitis has been reported with the use of macrolide antibiotics. Azithromycin suspension contains benzyl alcohol, sucrose, sulphites and sulphur dioxide. **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. Azithromycin may increase the concentrations of phosphorylated zidovudine, the clinically active

metabolite of Zidovudine, in peripheral blood mononuclear cells. Post-marketing cases of rhabdomyolysis in patients receiving azithromycin with statins have been reported. Post-marketing reports have been received of potentiated anticoagulation following co-administration of azithromycin and coumarin-type oral anticoagulants. Exercise caution when co-administering ciclosporin and oral azithromycin and carefully monitor ciclosporin levels. Co-administration of azithromycin and nelfinavir may result in increased azithromycin concentrations. Neutropenia was observed in subjects receiving concomitant treatment of azithromycin and rifabutin. Azithromycin should be administered with caution in combination with terfenadine. Concomitant administration of cisapride may cause an increase of QT interval prolongation, ventricular arrhythmias and Torsades de Pointes. Caution should be exercised when co-administering azithromycin with astemizole or alfentanil. 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). 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), carbamazepine, cimetidine, efavirenz, fluconazole, indinavir, methylprednisolone, midazolam, sildenafil, theophylline, triazolam and trimethoprim/sulfamethoxazole. **Pregnancy and lactation:** Should only be used during pregnancy if the benefit outweighs the risk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from azithromycin therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **Effects on ability to drive and use machines:** No or negligible influence on the ability to drive and use machines, but may cause dizziness and convulsions. **Adverse reactions:** Pseudomembranous colitis, pneumonia, gastroenteritis, leukopenia, neutropenia, thrombocytopenia, haemolytic anaemia, angioedema, hypersensitivity reaction, anaphylactic reaction, delirium, hallucination, syncope, myasthenia gravis, deafness, Torsades de Pointes, arrhythmia, ventricular tachycardia, electrocardiogram QT prolongation, gastritis, pancreatitis, hepatitis, cholestatic jaundice, hepatic failure, fulminant hepatitis, hepatic necrosis, AGEP, DRESS, Stevens-Jonson syndrome, toxic epidermal necrolysis and erythema multiforme. *Very Common*: Diarrhoea. *Common:* Headache, vomiting, abdominal pain, nausea, reduction in lymphocyte count and blood bicarbonate levels, and increase in eosinophil, basophil, monocyte and neutrophil count. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** Typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. Administration of medicinal charcoal and general symptomatic and supportive measures are indicated as required. **List Price:** Azithromycin 250mg Film-Coated Tablets, Pack of 4: £0.99; Azithromycin 500mg Film-Coated Tablets, Pack of 3: £1.09; Azithromycin 200mg/5ml Powder for Oral Suspension, 15ml Pack: £6.18. **Legal category:** POM. **Marketing Authorisation Number:** Azithromycin 250mg and 500mg Film-Coated Tablets: PL 00289/0584-0585; Azithromycin 200mg/5ml Powder for Oral Suspension: PL 00289/0973. **Marketing Authorisation Holder:** Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX. **Job Code:** MED-GB-00400. **Date of Preparation:** January 2025.