Abbreviated Prescribing Information for Use in the International Area
Based on the International Prescribing Information (GDS21/IPI09) and prepared to meet the requirements of the GSK International Pharmaceutical Promotional and Marketing Policy.

**AUGMENTIN 1 gm Tablets**

**Active Ingredients:** *AUGMENTIN* 1 g tablets: Each tablet contains 875 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate).

**Indications:** *AUGMENTIN* is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The β-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other β-lactam antibiotics. *AUGMENTIN* 1 g (875/125 mg) tablets are indicated for short-term treatment of bacterial infections of the upper and lower respiratory tract (including ENT), genito-urinary tract, skin and soft tissues, bones and joints, and other infections including dental infections, septic abortion, puerperal sepsis and intra-abdominal sepsis. For a list of susceptible organisms, refer to full prescribing information.

**Dosage and administration:** *Adults and Children over 12 years:* Severe infections: One *AUGMENTIN* 1 g tablet twice daily. *Children:* 1 g tablets are not recommended in children of 12 years and under. *Renal impairment:* Reduce dosage (see full prescribing information). *Hepatic impairment:* Dose with caution, monitor hepatic function at regular intervals. To minimise potential gastrointestinal intolerance and optimise absorption, administer at the start of a meal. Treatment should not be extended beyond 14 days without review. **Contraindications:** *AUGMENTIN* is contra-indicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins. *AUGMENTIN* is contra-indicated in patients with a previous history of *AUGMENTIN*-associated jaundice/hepatic dysfunction. **Warnings and Precautions:** Before initiating therapy with *AUGMENTIN* careful enquiry should be made concerning previous hypersensitivity reactions to penicillins or cephalosporins. *AUGMENTIN* should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further. Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving *AUGMENTIN* and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. In patients with renal impairment *AUGMENTIN* dosage should be adjusted. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin
crystalluria. **Interactions:** Concomitant use of probenecid is not recommended. Concomitant use with **AUGMENTIN** may result in increased and prolonged blood levels of amoxicillin but not of clavulanate. In common with other antibiotics, **AUGMENTIN** may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of **AUGMENTIN**. In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure. **Pregnancy and Lactation:** In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with **AUGMENTIN** may be associated with an increased risk of necrotising enterocolitis in neonates. Use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician. **AUGMENTIN** may be administered during the period of lactation. **Effects on Ability to Drive and Use Machines:** Adverse effects on the ability to drive or operate machinery have not been observed. **Adverse Reactions:** Infections and infestations: Common: Mucocutaneous candidiasis. Blood and lymphatic system disorders: Rare: leucopenia (including neutropenia) and thrombocytopenia. Very rare: agranulocytosis and haemolytic anaemia. Immune system disorders: Very rare: Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis. Nervous system disorders: Uncommon: Dizziness, headache. Very rare: Convulsions may occur in patients with impaired renal function or in those receiving high doses. Gastrointestinal disorders: Adults: Very common: Diarrhoea. Common: Nausea, vomiting. Children: Common: Diarrhoea, nausea, vomiting. All populations: Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking **AUGMENTIN** at the start of a meal. Uncommon: Indigestion. Very rare: Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). Black hairy tongue. Hepatobiliary disorders: Uncommon: A moderate rise in AST and/or ALT has been noted. Very rare: Hepatitis and cholestatic jaundice. Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects. Skin and subcutaneous tissue disorders: Uncommon Skin rash, pruritus, urticaria. Rare: Erythema multiforme. Very rare: Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (AGEP). If any hypersensitivity dermatitis reaction occurs,
treatment should be discontinued. Renal and urinary disorders: Very rare: Interstitial nephritis, crystalluria. **Overdose:** Disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed. **AUGMENTIN** can be removed from the circulation by haemodialysis. **Full Prescribing Information is available on request. Please read the full prescribing information prior to administration. Version GDS21/IPI09.**