Augmentin *ES*™

The recommended dose of Augmentin *ES*™ Suspension is 90/6.4 mg/kg/day in two divided doses.
Dosage: see chart below*

Augmentin *ES*™ is indicated for the treatment of acute otitis media in children aged at least 3 months and less than 40 kg body weight, caused or thought likely to be caused by penicillin-resistant Streptococcus pneumoniae.

Body Weight (kg)	Volume of Augmentin *ES*™ providing 90/6.4 mg/kg/day
8	3.0 ml twice daily
12	4.5 ml twice daily
16	6.0 ml twice daily
20	7.5 ml twice daily
24	9.0 ml twice daily
28	10.5 ml twice daily
32	12.0 ml twice daily
36	13.5 ml twice daily

* Augmentin *ES*™ Prescribing Information.

Therapeutic indications: Augmentin ES™ is indicated for the treatment of acute otitis media in children aged at least 3 months and less than 40 kg body weight, caused or thought likely to be caused by penicillin-resistant Streptococcus pneumoniae.

Augmentin ES™ – abbreviated PI:

For full information see MOH approved prescribing information

Generic name of the drug and active ingredients: 600 mg Amoxicillin as trihydrate /42.9 mg Clavulanic Acid as potassium salt (Potassium Clavulanate)/5 ml. **Dosage and methods of administration:** Doses are expressed throughout in terms of amoxicillin/clavulanic acid content except when doses are stated in terms of an individual component. The dose of Augmentin ES™ that is selected to treat an individual infection should take into account: • The expected pathogens and their likely susceptibility to antibacterial agents. • The severity and the site of the infection. • The age, weight and renal function of the patient as shown below. Treatment should not be extended beyond 14 days without review. **Adults and children ≥40 kg:** there is no experience with Augmentin ES™ suspension in adults and children ≥40 kg, and therefore no dose recommendation can be given. **Children <40 kg (aged ≥3 months):** The recommended dose of Augmentin ES™ suspension is 90/6.4 mg/kg/day in two divided doses. For full information on Augmentin ES™ dosing please refer to full PI as approved by MOH. There are no clinical data on Augmentin *ES*™ in children under 3 months of age. **Renal impairment:** No dose adjustment is required in patients with creatinine clearance (CrCl) greater than 30 ml/min.In patients with creatinine clearance less than 30 ml/min, the use of Augmentin ES™ is not recommended, as no recommendations for dose adjustments are available. **Hepatic impairment:** Dose with caution and monitor hepatic function at regular intervals. **Method of administration:** Augmentin ES™ is for oral use. Administer at the start of a meal to minimise potential gastrointestinal intolerance and optimise absorption of amoxicillin/clavulanic acid.Shake to loosen powder, add water as directed, invert and shake. Shake the bottle before each dose. **Contraindications:** Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients. History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam). History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid. **Special warnings and precautions for use:** Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or beta-lactam agents. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted. In the case that an infection is proven to be due to an amoxicillin-susceptible organisms(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance. Convulsions may occur in patients with impaired renal function or in those receiving high doses. Amoxicillin/clavulanic acid 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. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions .Prolonged use may occasionally result in overgrowth of non-susceptible organisms. The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (AGEP). This reaction requires Augmentin ES™ discontinuation and contra-indicates any subsequent administration of amoxicillin. Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment. 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. Antibiotic-associated colitis has been reported with nearly all antibacterial agents including amoxicillin and may range in severity from mild to life threatening. Should antibiotic-associated colitis occur, Augmentin ES™ should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. Anti-peristaltic drugs are contra-indicated in this situation. Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function is advisable during prolonged therapy. Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin/clavulanic acid. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation. 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. In patients with bladder catheters, a regular check of patency should be maintained. During treatment with amoxicillin, enzymatic glucose oxidase methods should be used whenever testing for the presence of glucose in urine because false positive results may occur with non-enzymatic methods. The presence of clavulanic acid in Augmentin may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test .Cross-reactions with non-Aspergillus polysaccharides and polyfuranoses with Bio-Rad Laboratories Platelia Aspergillus EIA test have been reported. Therefore, positive test results in patients receiving amoxicillin/clavulanic acid should be interpreted cautiously and confirmed by other diagnostic methods. Augmentin ES™ powder for oral suspension contains 2.72 mg of aspartame (E951) per ml, a source of phenylalanine. This medicine should be used with caution in patients with phenylketonuria. Augmentin ES™ powder for oral suspension contains maltodextrin (glucose). Patients with rare glucose-galactose malabsorption should not take this medicine. **Pregnancy and lactation:** Limited data on the use of amoxicillin/clavulanic acid during pregnancy in humans do not indicate an increased risk of congenital malformations. Use should be avoided during pregnancy, unless considered essential by the physician. Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast-fed infant). Consequently, diarrhea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge. **The most frequently occurring adverse drug reactions (ADRs):** The most commonly reported adverse drug reactions (ADRs) are diarrhoea, nausea and vomiting and mucocutaneous candidosis.

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Augmentin *ES*™

Amoxicillin as trihydrate 600 mg/5 ml
Clavulanic Acid as potassium salt 42.9 mg/5 ml

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