

## Augmentin<sup>®</sup> Prescribing Information

co-amoxiclav

(Please refer to the appropriate Summary of Product Characteristics for full details before prescribing)

**Augmentin** co-amoxiclav - tablets, suspension and intravenous formulations

### Indications:

- upper and lower respiratory tract infections
- genito-urinary and abdominal infections
- skin and soft tissue infections
- bone and joint infections
- prophylaxis against infections associated with major surgical procedures (for intravenous preparation only).

### Dosage:

Treatment should not exceed 14 days without review.

### Oral

- Adults and children over 40kg  
Suspensions: one 500 mg / 125 mg dose t.d.s.  
Tablets (375mg): one 250 mg / 125 mg dose t.d.s.  
Tablets (625mg): one 500 mg / 125 mg dose t.d.s.
- Children < 40kg  
Suspensions, Tablets (625mg): 20 mg / 5 mg / kg / day to 60 mg / 15 mg / kg / day in three divided doses.  
**Augmentin** 375mg film coated tablets are not recommended for use in children < 40kg.
- Children aged 6 years and below should preferably be treated with **Augmentin** suspension.

### Intravenous

#### For surgical prophylaxis:

- Adults: 1000 mg/200 mg to 2000 mg/200 mg at induction of anaesthesia for procedures < 1 hour.
- For longer procedures, up to 3 doses of 1000 mg/200 mg can be given in 24 hours.

#### For infections:

- Adults and children over 40kg: 1000/200mg 8-hourly.
- Children under 40kg:
  - aged 3 months and over: 25 mg/5 mg per kg every 8 hours
  - aged less than 3 months or weighing less than 4 kg: 25 mg/5 mg per kg every 12 hours

#### Renal and hepatic impairment:

- No dose adjustment is required in patients with creatinine clearance greater than 30ml/min.
- Dose with caution and monitor hepatic function at regular intervals.

#### Contra-indications:

- Hypersensitivity to any of the ingredients, penicillins or other β-lactam antibiotics, e.g. cephalosporins.
- History of co-amoxiclav-associated jaundice/hepatic dysfunction.

#### Special warnings and precautions:

- Anaphylactic reactions have been reported with penicillin.
- Use with caution in hepatic and renal impairment.
- Use should be avoided if infectious mononucleosis is suspected.
- Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

- Feverish generalised erythema with pustula at initiation of treatment may indicate onset of Acute Generalised Exanthematous Pustulosis (AGEP).
- Discontinue if antibiotic-associated colitis presents.
- Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.
- Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

#### Interactions:

- Prolongation of bleeding and prothrombin time reported; care in anticoagulant co-administration.
- Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.
- Concomitant use of probenecid is not recommended.

#### Pregnancy and lactation:

- Use in pregnancy not advised.
- Trace amounts found in breast milk.

#### Undesirable effects:

- Diarrhoea
- Nausea
- Vomiting
- Urticarial or erythematous rashes
- Stevens-Johnson syndrome
- Toxic epidermal necrolysis
- Serum-sickness like syndrome
- Acute Generalised Exanthematous Pustulosis (AGEP)
- Anaphylaxis
- Angioneurotic oedema
- Convulsions
- Antibiotic-associated colitis
- Candidiasis
- Overgrowth of non-susceptible organisms
- Blood dyscrasias

#### Presentations:

- **Augmentin** 375 mg Tablets, PL 00038/0270, containing co-amoxiclav 250/125 mg (21 tablet pack: £4.19).
- **Augmentin** 625 mg Tablets, PL 00038/0362, containing co-amoxiclav 500/125 mg (21 tablet pack: £8.00).
- **Augmentin-Duo** 400/57 Suspension Sugar-Free, PL 10592/0070, containing co-amoxiclav 400/57 mg per 5ml as powder (35 ml bottle with syringe measure: £4.13; 70ml bottle: £5.79).
- **Augmentin** 125/31 SF Suspension, PL 00038/0298, containing co-amoxiclav 125/31 mg per 5 ml as powder (100ml bottle: £4.08).
- **Augmentin** 250/62 SF Suspension, PL 00038/0337, containing co-amoxiclav 250/62 mg per 5ml a powder (100ml bottle: £5.74).
- Amoxicillin is present as the trihydrate and clavulanic acid as potassium clavulanate.
- **Augmentin** intravenous, PL 00038/0320, containing co-amoxiclav 500/100 or 1000/200 in 600 mg or 1.2g vials (10 x 600ml vials: £13.01; 10 x 1.2g vials: £26.02). Amoxicillin is present as amoxicillin sodium and clavulanic acid as potassium clavulanate.

## Dear Doctor,

Cases of colds and flu occur more frequently during the autumn and winter. Patients at risk of complications - such as upper and lower respiratory tract infections - may well come to the surgery to see you more often. Within a family, infections can be transferred easily from one member to another and both children and older members of the family may be at greater risk from these diseases. How can you help vulnerable patients infected with respiratory infections? Take a look at our case studies of family members. This is the Smith family. Over the next few weeks they could be typical of the type of family you might see in your consulting room.



# AUGMENTIN<sup>®</sup>

co-amoxiclav (amoxicillin and clavulanic acid)



The Family Smith from right to left:

Connor, Catherine, Christopher, Ellie, Dominic, Daniel, Charlotte, Alex, Peter and Agnes. They are a busy and active family, but even so they can all get ill during the winter, independent of age and gender.



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Christopher woke up crying several times during the night, complaining of pain in his ear. His parents put a warm poultice on it but the pain didn't go away. His forehead felt hot, so they measured his temperature and, as it was 37.9 °C, they were worried. Christopher's parents were also concerned about his brother Dominic; usually a good eater, he had lost his appetite for the last 4 days, and on the way home from nursery he fell asleep in the car which was unusual. They decided to phone the GP and made an appointment for both boys to be examined. Dominic cried a lot from pain during examination; Christopher was in pain too but he didn't cry. The GP diagnosed Otitis in both boys. He prescribed Augmentin DUO syrup™ twice a day for both Christopher and Dominic.

Charlotte came home from work one evening complaining of feeling unwell and of loin pain. For the past 5 days, she had pain when passing urine. She had also to go to the toilet more frequently during the day. So Charlotte went to see her doctor.

The doctor did urine tests and diagnosed an acute uncomplicated pyelonephritis following a cystitis episode. She prescribed Augmentin 625 mg tablets three times per day for 14 days, a urine culture with susceptibility testing<sup>4</sup> and a renal ultrasound examination to rule out urinary obstruction or renal stone disease.<sup>4</sup>



# AUGMENTIN® DUO Syrup

co-amoxiclav (amoxicillin and clavulanic acid)



# AUGMENTIN® 625 mg Tablets

co-amoxiclav (amoxicillin and clavulanic acid)

**SYMPTOMS**  
Loss of appetite, tiredness, pain on examination

**DIAGNOSIS**  
Bilateral Acute Otitis Media

**TREATMENT**  
Augmentin DUO Suspension 125/31 twice a day\*

**SYMPTOMS**  
Headache, fever, earache, touching the ear

**DIAGNOSIS**  
Acute Otitis Media (AOM)

**TREATMENT**  
Augmentin DUO Suspension 250/62 twice a day\*

**SYMPTOMS**<sup>4</sup>  
Flank pain, nausea and vomiting, fever (>38°C), or costovertebral angle tenderness, with or without symptoms of cystitis

**DIAGNOSIS**  
Acute pyelonephritis secondary to cystitis

**TREATMENT**  
Augmentin tablets 625 mg three times a day\*

\* the Augmentin dose is only informative: it should take into account the expected pathogens, the severity of the infection, the age, weight and renal function of the patient<sup>1</sup>

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### Symptoms:

Fever, headache, pain in the ear on either side, loss of appetite, sleepiness, crying, the child repeatedly touches the ear.<sup>2</sup>

### Main differential diagnosis:

Otitis media with effusion (OME) that refers to middle ear fluid that is not infected.<sup>2</sup> The AOM clinical picture is fairly typical. Tenderness of the tragus on physical examination is of special note. In doubtful cases the otoscope image serves as a guide, in this case, it showed a distinctly red, yellow, and cloudy tympanic membrane.<sup>2</sup> Diagnosis must extend to whether the case is "only" acute otitis media or already has complications. Main complications: meningitis, mastoiditis

### Management:

Children diagnosed with acute otitis media should not routinely be prescribed antibiotics as the initial treatment. But if an antibiotic is used, broad spectrum antibiotics such as amoxicillin, or amoxicillin with clavulanic acid, are the drugs of choice with *S. pneumoniae* and *H. influenzae*.<sup>3</sup>

### Symptoms:

Flank pain, nausea and vomiting, fever (> 38°C), or costovertebral angle tenderness, with or without symptoms of cystitis: pain on passing urine, increased frequency of passing urine, cloudy urine, abdominal pain, unpleasant smelling urine.<sup>4</sup>

### Differential diagnosis:

Particularly if dipstick tests are negative: Pelvic inflammatory disease. Appendicitis. Renal calculi.<sup>5</sup>

### Management:

A urine culture is recommended before treatment, so allowing antimicrobial therapy to be adjusted if necessary.\* The HPA recommend ciprofloxacin and co-amoxiclav for the empirical treatment of acute pyelonephritis.<sup>6</sup> When starting an empirical antibiotic treatment, consideration should be given to official guidance on appropriate use of antibacterial agent. In mild and moderate cases of acute uncomplicated pyelonephritis, oral therapy of 10-14 days is usually sufficient.<sup>4</sup> A sufficient fluid intake should be recommended.<sup>6</sup>

#### REFERENCE:

1. Augmentin SmPC 2012
2. NHS Clinical Knowledge Summaries at [http://www.cks.nhs.uk/otitis\\_media\\_acute/management/scenario\\_diagnosis/differential\\_diagnosis#376066006](http://www.cks.nhs.uk/otitis_media_acute/management/scenario_diagnosis/differential_diagnosis#376066006)
3. SIGN: Diagnosis and management of childhood otitis media in primary care Section 3: Medical treatment at <http://www.sign.ac.uk/guidelines/fulltext/66/section3.html>
4. 2011 EAU guidelines on urological infections available at [http://www.uroweb.org/gls/pdf/17\\_Urological%20infections\\_LR%2011.pdf](http://www.uroweb.org/gls/pdf/17_Urological%20infections_LR%2011.pdf)
5. [http://www.cks.nhs.uk/pyelonephritis\\_acute/management/scenario\\_diagnosis/view\\_full\\_scenario#367714006](http://www.cks.nhs.uk/pyelonephritis_acute/management/scenario_diagnosis/view_full_scenario#367714006)
6. [http://www.cks.nhs.uk/pyelonephritis\\_acute/management/scenario\\_pyelonephritis\\_acute#-371694](http://www.cks.nhs.uk/pyelonephritis_acute/management/scenario_pyelonephritis_acute#-371694)

