For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

I.V. AUGMENTIN 300mg (Paediatric) / 600mg / 1.2g

1. GENERIC NAME

Amoxycillin and Potassium Clavulanate for Injection IP 300mg / 600mg / 1.2g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

I.V. AUGMENTIN 300 mg (Paediatric)
Each vial contains:
Amoxycillin Sodium IP equivalent to Amoxycillin 250 mg
Potassium Clavulanate IP equivalent to Clavulanic Acid 50 mg

I.V. AUGMENTIN 600 mg
Each vial contains:
Amoxycillin Sodium IP equivalent to Amoxycillin 500 mg
Potassium Clavulanate IP equivalent to Clavulanic Acid 100 mg

I.V. AUGMENTIN 1.2 g
Each vial contains:
Amoxycillin Sodium IP equivalent to Amoxycillin 1000 mg
Potassium Clavulanate IP equivalent to Clavulanic Acid 200 mg

List of Excipients
None

3. DOSAGE FORM AND STRENGTH

Sterile powder for injection.

For information on strengths see *2. Qualitative and Quantitative Composition*.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

AUGMENTIN should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.

I.V. AUGMENTIN 300mg (Paediatric)/ 600mg/ 1.2g is indicated for short-term treatment of bacterial infections at the following sites:

Upper respiratory tract infections (including ENT) e.g. recurrent tonsillitis, sinusitis, otitis media.

Lower respiratory tract infections e.g. acute exacerbation of chronic obstructive pulmonary disease (AECOPD)/acute exacerbation of chronic bronchitis (AECB), lobar and bronchopneumonia.

Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.

Skin and soft tissue infections e.g. boils, abscesses, cellulitis, wound infections.

Bone and joint infections e.g. osteomyelitis.

Other infections e.g. intra-abdominal sepsis.

I.V. AUGMENTIN 300mg (Paediatric)/ 600mg/ 1.2g is also indicated for prophylaxis against infection which may be associated with major surgical procedures such as gastrointestinal, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract.

Susceptibility to *AUGMENTIN* will vary with geography and time (see *5. Pharmacological Properties, Pharmacodynamic Properties* for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Infections caused by amoxycillin-susceptible organisms are amenable to *AUGMENTIN* treatment due to its amoxycillin content. Mixed infections caused by amoxycillin-susceptible organisms in conjunction with *AUGMENTIN*-susceptible β-lactamase producing organisms may therefore be treated with *AUGMENTIN*.

4.2 Posology and Method of Administration

Dosage for the treatment of infections

Adults and children over 12 years	Usually 1.2 g eight hourly. In more serious infections, increase frequency to six-hourly intervals.
Children 3 months-12 years	Usually 30 mg/kg* *AUGMENTIN* eight hourly. In more serious infections, increase frequency to six-hourly intervals.
Children 0-3 months	30 mg/kg* *AUGMENTIN* every 12 hours in premature infants and in full term infants during the perinatal period, increasing to eight hours thereafter.

* Each 30 mg *I.V. AUGMENTIN* contains 25 mg amoxycillin and 5 mg clavulanate.

Adult dosage for surgical prophylaxis

The usual dose is 1.2 g *I.V. AUGMENTIN* given at the induction of anaesthesia. Operations where there is a high risk of infection, e.g. colorectal surgery, may require three, and up to four, doses of 1.2 g *I.V. AUGMENTIN* in a 24-hour period. These doses are usually given at 0, 8, 16 (and 24) hours. This regimen can be continued for several days if the procedure has a significantly increased risk of infection.

Clear clinical signs of infection at operation will require a normal course of intravenous or oral *AUGMENTIN* therapy post-operatively.

Dosage in Renal Impairment

Adults

Mild impairment (creatinine clearance >30 mL/min)	Moderate impairment (creatinine clearance 10-30 mL/min)	Severe impairment (creatinine clearance <10 mL/min)
No change in dosage	1.2 g IV stat, followed by 600 mg IV 12 hourly	1.2 g IV stat, followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of *AUGMENTIN* and an additional 600 mg IV dose may need to be given during dialysis and at the end of dialysis

Children

Similar reductions in dosage should be made for children.

Dosage in Hepatic Impairment

Administer with caution; monitor hepatic function at regular intervals.

Administration

I.V. AUGMENTIN 600 mg/1.2 g may be administered either by intravenous injection or by intermittent infusion. *I.V. AUGMENTIN 600 mg/ 1.2 g* is not suitable for intramuscular administration.

I.V. AUGMENTIN 300 mg (Paediatric) should be administered only by intravenous injection. It is not suitable for intermittent infusion or intramuscular administration.

4.3 Contraindications

AUGMENTIN is contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins.

AUGMENTIN is contraindicated in patients with a previous history of *AUGMENTIN*-associated jaundice/hepatic dysfunction.

4.4 Special Warnings and Precautions for Use

Before initiating therapy with *AUGMENTIN*, careful enquiry should be made concerning previous hypersensitivity reactions, cephalosporins, or other allergens.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity (see *4.3 Contraindications*). Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such

reactions can include chest pain occurring in association with an allergic reaction to *AUGMENTIN*(see *4.8 Undesirable Effects)*. Drug-induced enterocolitis syndrome has been reported mainly in children receiving *AUGMENTIN* (see *4.8 Undesirable Effects*). Drug-induced enterocolitis syndrome is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after medicinal product administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, lethargy, diarrhoea, hypotension or leucocytosis with neutrophilia. In severe cases, drug-induced enterocolitis syndrome can progress to shock. If an allergic reaction occurs, *AUGMENTIN* therapy must be discontinued and appropriate alternative therapy instituted.

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous (i.v.) steroids and airway management (including intubation) may also be required.

Haemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) has been reported in patients receiving amoxicillin-clavulanate (see *section 4.8 Undesirable Effects*). HLH/MAS is a syndrome of pathological immune activation, which can be life threatening. Clinical signs and symptoms of HLH/MAS include fever, rash, neurological symptoms, hepatosplenomegaly, lymphadenopathy, cytopenias, high serum ferritin, hypertriglyceridaemia and abnormalities of liver function and coagulation.

Patients who develop these signs and symptoms should be immediately evaluated and HLH/MAS diagnosis considered. Amoxicillin-clavulanate therapy should be discontinued unless an alternative aetiology for HLH/MAS can be established.

Changes in liver function tests have been observed in some patients receiving *AUGMENTIN*. The clinical significance of these changes is uncertain but *AUGMENTIN* should be used with caution in patients with evidence of hepatic dysfunction.

Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.

In patients with renal impairment *AUGMENTIN* dosage should be adjusted as recommended in *4.2 Posology and Method of Administration* section.

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 amoxycillin.

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 International Normalized Ratio (INR)] has been reported rarely in patients receiving *AUGMENTIN* and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed

concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet.

In patients with reduced urine output crystalluria has been observed very rarely, predominantly with parenteral therapy. During administration of high doses of amoxycillin it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxycillin crystalluria (see *4.9 Overdose*).

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.

4.5 Drug Interactions

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxycillin. Concomitant use with *AUGMENTIN* may result in increased and prolonged blood levels of amoxycillin but not of clavulanate.

Concomitant use of allopurinol during treatment with amoxycillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of *AUGMENTIN* and allopurinol.

In common with other antibiotics, *AUGMENTIN* may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

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.

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxycillin. 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 amoxycillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure.

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

4.6 Use in Special Populations

Pregnancy

Reproduction studies in animals (mice and rats) with orally and parenterally administered *AUGMENTIN* have shown no teratogenic effects. In a single study in women with preterm, 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. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

Lactation

AUGMENTIN may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no detrimental effects for the infant.

4.7 Effects on Ability to Drive and Use Machines

Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable Effects

Data from large clinical trials were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e., those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than a true frequency.

The following convention has been used for the classification of frequency:

Very common ≥ 1/10
Common ≥ 1/100 and < 1/10
Uncommon ≥ 1/1,000 and < 1/100
Rare ≥ 1/10,000 and < 1/1,000
Very rare < 1/10,000

Infections and infestations

Common	Mucocutaneous candidiasis

Blood and lymphatic system disorders

Rare	Reversible leucopenia (including neutropenia) and thrombocytopenia
Very rare	Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time

Immune system disorders

Very rare	Haemophagocytic lymphohistiocytosis/macrophage activation syndrome, anaphylaxis, angioneurotic oedema, (see *4.4 Special Warnings and Precautions for Use*), serum sickness-like syndrome, hypersensitivity vasculitis (see also *Skin and subcutaneous tissue disorders*).

Nervous system disorders

Uncommon	Dizziness, headache
Very rare	Aseptic meningitis, convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Cardiac disorders

Very Rare	Kounis syndrome (see *4.4 Special Warnings and Precautions for Use*).

Vascular disorders

Rare	Thrombophlebitis at the site of injection

Gastrointestinal disorders

Common	Diarrhoea
Uncommon	Nausea, vomiting, indigestion
Very rare	Antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis see *4.4 Special Warnings and Precautions for Use*) are less likely to occur after parenteral administration. Drug-induced enterocolitis syndrome (see *4.4 Special Warnings and Precautions for Use*)

Hepatobiliary disorders

Uncommon	A moderate rise in AST and/or ALT has been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown.
Very rare	Hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporins.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.

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), drug reaction with eosinophilia and systemic symptoms (DRESS), and symmetrical drug-related intertriginous and flexural exanthema (SDRIFE) (baboon syndrome) (see also *Immune system disorders*). If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued. Linear IgA disease

Renal and urinary disorders

Very rare	Interstitial nephritis, crystalluria (see *4.9 Overdose*)

4.9 Overdose

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water electrolyte balance.

Amoxycillin crystalluria, in some cases leading to renal failure, has been observed (see *4.4 Special Warnings and Precautions for Use*).

AUGMENTIN can be removed from the circulation by haemodialysis.

Amoxycillin has been reported to precipitate in bladder catheters after intravenous administration of large doses. A regular check of patency should be maintained.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

Amoxycillin is a semisynthetic antibiotic with a broad spectrum of antibacterial activity against many gram-positive and gram-negative micro-organisms. Amoxycillin is, however, susceptible to degradation by beta-lactamases and therefore the spectrum of activity of amoxycillin alone does not include organisms which produce these enzymes.

Clavulanic acid is a beta-lactam, structurally related to the penicillins, which possesses the ability to inactivate a wide range of beta-lactamase enzymes commonly found in micro-organisms resistant to penicillins and cephalosporins. In particular, it has good activity against the clinically important plasmid mediated beta-lactamases frequently responsible for transferred drug resistance. It is generally less effective against chromosomally-mediated type 1 beta-lactamases.

The presence of clavulanic acid in amoxycillin-clavulanate formulations protects amoxycillin from degradation by beta-lactamase enzymes and effectively extends the antibacterial spectrum of amoxycillin to include many bacteria normally resistant to amoxycillin and other penicillins

and cephalosporins. Thus amoxycillin-clavulanate possesses the distinctive properties of a broad spectrum antibiotic and a beta-lactamase inhibitor.

5.2 Pharmacodynamic Properties

ATC Code: J01CR02
Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in *AUGMENTIN* anticipates this defence mechanism by blocking the ß-lactamase enzymes, thus rendering the organisms susceptible to amoxycillin's rapid bactericidal effect at concentrations readily attainable in the body.

Clavulanate by itself has little antibacterial activity; however, in association with amoxycillin as *AUGMENTIN,* it produces an antibiotic agent of broad spectrum with wide application in hospital and general practice.

In the list below, organisms are categorised according to their in *vitro* susceptibility to *AUGMENTIN*.

In vitro* susceptibility of micro-organisms to *AUGMENTIN
Where clinical efficacy of *AUGMENTIN* has been demonstrated in clinical trials this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxycillin, it can be considered susceptible to *AUGMENTIN*.
Commonly susceptible species
Gram-positive aerobes: *Bacillius anthracis* *Enterococcus faecalis* *Gardnerella vaginalis* *Listeria monocytogenes* *Nocardia asteroides* *Streptococcus pneumoniae**† *Streptococcus pyogenes**† *Streptococcus agalactiae**† Viridans group streptococcus† *Streptococcus* spp. (other β-hemolytic)*† *Staphylococcus aureus* (methicillin susceptible)* *Staphylococcus saprophyticus* (methicillin susceptible) Coagulase negative staphylococcus (methicillin susceptible)
Gram-negative aerobes: *Bordetella pertussis* *Haemophilus influenzae** *Haemophilus parainfluenzae* *Helicobacter pylori* *Moraxella catarrhalis** *Neisseria gonorrhoeae* *Pasteurella multocida* *Vibrio cholerae*

Other: *Borrelia burgdorferi* *Leptospira ictterohaemorrhagiae* *Treponema pallidum*
Gram positive anaerobes: *Clostridium* spp. *Peptococcus niger* *Peptostreptococcus magnus* *Peptostreptococcus micros* *Peptostreptococcus* spp.
Gram-negative anaerobes: *Bacteroides fragilis* *Bacteroides* spp. *Capnocytophaga* spp. *Eikenella corrodens* *Fusobacterium nucleatum* *Fusobacterium* spp. *Porphyromonas* spp. *Prevotella* spp.
Species for which acquired resistance may be a problem
Gram-negative aerobes: *Escherichia coli** *Klebsiella oxytoca* *Klebsiella pneumoniae** *Klebsiella* spp. *Proteus mirabilis* *Proteus vulgaris* *Proteus* spp. *Salmonella* spp. *Shigella* spp.
Gram-positive aerobes: *Corynebacterium* spp. *Enterococcus faecium*
Inherently resistant organisms
Gram-negative aerobes: *Acinetobacter* spp. *Citrobacter freundii* *Enterobacter* spp. *Hafnia alvei* *Legionella pneumophila* *Morganella morganii* *Providencia* spp. *Pseudomonas* spp. *Serratia* spp. *Stenotrophomas maltophilia* *Yersinia enterolitica*
Others: *Chlamydia pneumoniae* *Chlamydia psittaci* *Chlamydia* spp.

Coxiella burnetti *Mycoplasma* spp.

5.3 Pharmacokinetic Properties

The pharmacokinetics of the two components of *AUGMENTIN* are closely matched. Both clavulanate and amoxycillin have low levels of serum binding; about 70% remains free in the serum.

Doubling the dosage of *AUGMENTIN* approximately doubles the serum levels achieved.

6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology and Pharmacology

No further information of relevance.

7. DESCRIPTION

AUGMENTIN (beta-lactam antibacterial penicillin coformulated with a beta- lactamase inhibitor) is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxycillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics.

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

I.V. AUGMENTIN 300mg (Paediatric)/ 600mg/ 1.2g should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.

If *AUGMENTIN* is prescribed concurrently with an aminoglycoside, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions.

8.2 Shelf Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Clear glass vial in a carton.

All presentations may not be marketed in the country.

8.4 Storage and Handling Information

300 mg vial: Store at a temperature between 2°C to 8°C.

600 mg vial: Store at a temperature not exceeding 25°C.

1.2 g vial: Store at a temperature not exceeding 25°C.

Use immediately after reconstitution. Do not freeze.

Keep out of reach of children.

Single Use Vial Only

300 mg vial: To reconstitute dissolve in 5 ml sterile Water for Injections IP (Final volume 5.25 ml)

600 mg vial: To reconstitute dissolve in 10 ml sterile Water for Injections IP (Final volume 10.5 ml)

1.2 g vial: To reconstitute dissolve in 20 ml sterile Water for Injections IP (Final volume 20.9 ml)

A transient pink coloration may or may not appear during reconstitution. Reconstituted solutions are normally colourless or a yellow colour.

Intravenous Injection:

The stability of *I.V. AUGMENTIN 300mg (Paediatric) / 600mg/ 1.2g* solution is concentration dependent, thus *I.V. AUGMENTIN 300mg (Paediatric) / 600mg/ 1.2g* should be used immediately upon reconstitution and given by slow intravenous injection over a period of 3-4 minutes. *I.V. AUGMENTIN 300mg (Paediatric) / 600mg/ 1.2g* solutions should be used within 20 minutes of reconstitution. *AUGMENTIN* may be injected directly into a vein or via a drip tube.

Intravenous Infusion:

Alternatively, *I.V. AUGMENTIN 600 mg and 1.2 gm* may be infused in Water for Injections IP or Sodium Chloride Intravenous Injection IP (0.9% w/v). Add, without delay*, 600 mg reconstituted solution to 50 ml infusion fluid or 1.2 g reconstituted solution to 100 ml infusion fluid (e.g. using a minibag or in-line burette). Infuse over 30-40 minutes and complete within four hours of reconstitution. For other appropriate infusion fluids, see *Stability and Compatibility* section.

*Solutions should be made up to full infusion volume immediately after reconstitution.

Any residual antibiotic solutions should be discarded.

Therapy can be started parenterally and continued with an oral preparation. Treatment should not be extended beyond 14 days without review.

Stability and Compatibility

Intravenous infusions of *I.V. AUGMENTIN 600 mg and 1.2 gm* may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature (25°C) in the recommended volume of the following infusion fluids. If reconstituted and maintained at room temperature, infusions should be completed within the times stated.

Intravenous infusion fluids	***Stability period at 25°C***
Water for Injections IP	4 hours
Sodium Chloride Intravenous Infusion IP (0.9% w/v)	4 hours
Sodium Lactate Intravenous Infusion IP (one-sixth molar)	4 hours
Compound Sodium Chloride Intravenous Infusion IP (Ringer's Solution)	3 hours
Compound Sodium Lactate Intravenous Infusion IP (Ringer-Lactate Solution; Hartmann's Solution)	3 hours
Potassium Chloride and Sodium Chloride Intravenous Infusion IP	3 hours

Reconstituted solutions should not be frozen.

I.V. AUGMENTIN 600 mg and 1.2 gm is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions of *I.V. AUGMENTIN 600 mg and 1.2 gm* should therefore not be added to such infusions but may be injected into the drip tubing over a period of 3-4 minutes.

For storage at 5°C, the reconstituted solution should be added to pre-refrigerated infusion bags which can be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperature.

Intravenous infusion fluids	***Stability period at 5°C***
Water for Injections IP	8 hours
Sodium Chloride Intravenous Infusion IP (0.9% w/v)	8 hours

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *I.V. AUGMENTIN 300mg (Paediatric)/ 600mg/ 1.2g*. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.

For further information, please contact:

GlaxoSmithKline Pharmaceuticals Limited.
Registered Office:
Dr. Annie Besant Road, Worli,
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

12-NOV-2025

Version: AUG-IV/PI/IN/2025/01

Adapted from Amoxicillin-clavulanate (Intravenous) GDS version 35/IPI version 16 dated 10 July 2025.