1. **GENERIC NAME**

Amoxycillin and Potassium Clavulanate Oral Suspension IP

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5 mL of the reconstituted suspension contains:

Amoxycillin Trihydrate IP equivalent to Amoxycillin 400 mg.
Potassium Clavulanate Diluted IP equivalent to Clavulanic Acid 57 mg

The dry powder for reconstitution may or may not be co-packaged with 30 mL pack of Sterile Purified Water U.S.P for reconstitution.

3. **DOSAGE FORM AND STRENGTH**

Dry powder for reconstitution in water to form an oral sugar free suspension.

4. **CLINICAL PARTICULARS**

4.1. **Therapeutic Indications**

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

*AUGMENTIN DDS*, for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxycillin resistant beta-lactamase producing strains are suspected as the cause.

**Upper Respiratory Tract Infections (including ENT)** e.g. recurrent tonsilitis, sinusitis, otitis media

**Lower Respiratory Tract Infections** e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia

**Urinary Tract Infections** e.g. cystitis, urethritis, pyelonephritis

**Skin and Soft Tissue Infections** e.g. cellulitis, animal bites

**Dental Infections** e.g. severe dental abscess with spreading cellulitis

Susceptibility to *AUGMENTIN* will vary with geography and time (see 5 Pharmacological Properties, 5.2 Pharmacodynamic Properties for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Mixed infections caused by amoxycillin-susceptible organisms in conjunction with *AUGMENTIN* susceptible beta-lactamase-producing organisms may be treated with *AUGMENTIN DDS*. These infections should not require the addition of another antibiotic resistant to beta-lactamases.
4.2. Posology and Method of Administration

Dosage depends on the age, weight and renal function of the patient and the severity of the infection.

Dosages are expressed throughout in terms of amoxycillin/clavulanate content except when doses are stated in terms of an individual component.

To minimize the potential gastrointestinal intolerance, administer at the start of a meal. The absorption of AUGMENTIN is optimized when taken at the start of a meal.

Treatment should not exceed 14 days without review.

Therapy can be started parenterally and continued with an oral preparation.

For preparation of the suspension see 8.4 Storage and Handling Information.

The usual recommended daily dosage is:

- Lower dose: 25/3.6 to 45/6.4 mg/kg/day in two divided doses for mild to moderate infections (upper respiratory tract infections e.g. recurrent tonsillitis, lower respiratory infections and skin and soft tissue infections)

- Higher dose: 45/6.4 to 70/10 mg/kg/day in two divided doses for the treatment of more serious infections (upper respiratory tract infections e.g. otitis media and sinusitis, lower respiratory tract infections e.g. bronchopneumonia and urinary tract infections)

No clinical data are available on doses above 45/6.4 mg/kg/day in children under 2 years.

There are no clinical data for AUGMENTIN suspensions to make dosage recommendations for children under 2 months old.

The tables below give dosage guidance for children.

**Children 2 years and over**

<table>
<thead>
<tr>
<th>AUGMENTIN DDS Suspension 457 mg/5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body weight (kg)</strong></td>
</tr>
<tr>
<td>12 to 16</td>
</tr>
<tr>
<td>17 to 26</td>
</tr>
<tr>
<td>27 to 35</td>
</tr>
<tr>
<td>36 to &lt;40</td>
</tr>
</tbody>
</table>

**Children aged 2 months to under 2 years**

<table>
<thead>
<tr>
<th>AUGMENTIN DDS Suspension 457 mg/5 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body Weight (kg)</strong></td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>
### Renal Impairment

No adjustment in dose is required in patients with creatinine clearance greater than 30 mL/min.

*AUGMENTIN DDS* is not recommended in patients with a creatinine clearance of less than 30 mL/min.

### Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals. There is, as yet, insufficient evidence on which to base a dosage recommendation.

### 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 to penicillins, 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). 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.

*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

<p>| | | |</p>
<table>
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<tbody>
<tr>
<td>4</td>
<td>0.6</td>
<td>1.1</td>
</tr>
<tr>
<td>5</td>
<td>0.8</td>
<td>1.4</td>
</tr>
<tr>
<td>6</td>
<td>0.9</td>
<td>1.7</td>
</tr>
<tr>
<td>7</td>
<td>1.1</td>
<td>2.0</td>
</tr>
<tr>
<td>8</td>
<td>1.3</td>
<td>2.3</td>
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<tr>
<td>9</td>
<td>1.4</td>
<td>2.5</td>
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<tr>
<td>10</td>
<td>1.6</td>
<td>2.8</td>
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<tr>
<td>11</td>
<td>1.7</td>
<td>3.1</td>
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<tr>
<td>12</td>
<td>1.9</td>
<td>3.4</td>
</tr>
<tr>
<td>13</td>
<td>2.0</td>
<td>3.7</td>
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<tr>
<td>14</td>
<td>2.2</td>
<td>3.9</td>
</tr>
<tr>
<td>15</td>
<td>2.3</td>
<td>4.2</td>
</tr>
</tbody>
</table>
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.

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 DDS is not recommended.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the 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).

AUGMENTIN DDS contains 12.5 mg aspartame per 5 mL dose and therefore care should be taken in patients with phenylketonuria.

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.

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.

4.6. Use in Special Populations

Pregnancy and Lactation
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.

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.

**Renal Impairment**

No adjustment in dose is required in patients with creatinine clearance greater than 30 mL/min.

AUGMENTIN DDS is not recommended in patients with a creatinine clearance of less than 30 mL/min.

**Hepatic Impairment**

Dose with caution; monitor hepatic function at regular intervals. There is, as yet, insufficient evidence on which to base a dosage recommendation.

**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 $\geq 1/10$
- Common $\geq 1/100$ to $< 1/10$
- Uncommon $\geq 1/1000$ to $< 1/100$
- Rare $\geq 1/10,000$ to $< 1/1000$
- 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 Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis

**Nervous system disorders:**

Uncommon Dizziness, headache

Very rare Reversible hyperactivity, aseptic meningitis, convulsions. 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) - (See 4.4 Special Warnings and Precautions for use.)

Black hairy tongue

Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

**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. 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), and drug reaction with eosinophilia and systemic symptoms (DRESS)

If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.

**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.

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 I 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**

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in *AUGMENTIN* suspension anticipates this defence mechanism by blocking
the beta-lactamase enzymes, thus rendering the organisms sensitive 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.

<table>
<thead>
<tr>
<th>In vitro susceptibility of micro-organisms to AUGMENTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where clinical efficacy of AUGMENTIN has been demonstrated in clinical trials this is indicated with an asterisk (*).</td>
</tr>
<tr>
<td>Organisms that do not produce beta-lactamase are identified (with †). If an isolate is susceptible to amoxycillin, it can be considered susceptible to AUGMENTIN.</td>
</tr>
</tbody>
</table>

### Commonly susceptible species

**Gram-positive aerobes:**
- Bacillus anthracis
- Enterococcus faecalis
- Listeria monocytogenes
- Nocardia asteroides
- *Streptococcus pyogenes*†
- *Streptococcus agalactiae*†
- *Streptococcus* spp. (other beta-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.
**Species for which acquired resistance may be a problem**

<table>
<thead>
<tr>
<th>Gram-negative aerobes:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Escherichia coli</em></td>
</tr>
<tr>
<td><em>Klebsiella oxytoca</em></td>
</tr>
<tr>
<td><em>Klebsiella pneumoniae</em></td>
</tr>
<tr>
<td><em>Proteus mirabilis</em></td>
</tr>
<tr>
<td><em>Proteus vulgaris</em></td>
</tr>
<tr>
<td><em>Proteus</em> spp.</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gram-positive aerobes:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Corynebacterium</em> spp.</td>
</tr>
<tr>
<td><em>Enterococcus faecium</em></td>
</tr>
<tr>
<td><em>Streptococcus pneumoniae</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inherently resistant organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram-negative aerobes:</td>
</tr>
<tr>
<td><em>Acinetobacter</em> spp.</td>
</tr>
<tr>
<td><em>Citrobacter freundii</em></td>
</tr>
<tr>
<td><em>Enterobacter</em> spp.</td>
</tr>
<tr>
<td><em>Hafnia alvei</em></td>
</tr>
<tr>
<td><em>Legionella pneumophila</em></td>
</tr>
<tr>
<td><em>Morganella morganii</em></td>
</tr>
<tr>
<td><em>Providencia</em> spp.</td>
</tr>
<tr>
<td><em>Pseudomonas</em> spp.</td>
</tr>
<tr>
<td><em>Serratia</em> spp.</td>
</tr>
<tr>
<td><em>Stenotrophomonas maltophilia</em></td>
</tr>
<tr>
<td><em>Yersinia enterolitica</em></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Others:</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Chlamydia pneumoniae</em></td>
</tr>
<tr>
<td><em>Chlamydia psittaci</em></td>
</tr>
<tr>
<td><em>Chlamydia</em> spp.</td>
</tr>
<tr>
<td><em>Coxiella burnetti</em></td>
</tr>
<tr>
<td><em>Mycoplasma</em> spp.</td>
</tr>
</tbody>
</table>

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 beta-lactamase producing organisms may therefore be treated with AUGMENTIN.

5.3. Pharmacokinetic Properties

**Absorption:**
The two components of AUGMENTIN DDS, amoxycillin and clavulanate, are each fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of AUGMENTIN is optimised when taken at the start of a meal.

Amoxycillin serum concentrations achieved with AUGMENTIN are similar to those produced by the oral administration of equivalent doses of amoxycillin alone.

**Distribution:**

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**

**General 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.

**Chemical Structure**

AUGMENTIN is a coformulation of amoxycillin trihydrate and potassium clavulanate.

**Amoxycillin trihydrate**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>(2S,5R,6R)-6-[(R)-(2-amino-2-(p-hydroxyphenyl) acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.</th>
</tr>
</thead>
</table>
| Structural formula | \[
\begin{align*}
\text{HO} & \quad \text{NH}_2 \\
\text{N} & \quad \text{N} \\
\text{S} & \quad \text{H} \\
\text{CH}_3 & \\
\text{CH}_3 & \\
\text{CO}_2\text{H} & \\
\end{align*}
\] \quad 0.3\text{H}_2\text{O}
\]

<table>
<thead>
<tr>
<th>Molecular formula</th>
<th>C_{16}H_{19}N_{3}O_{5}S·3\text{H}_2\text{O}</th>
</tr>
</thead>
</table>
| Relative molecular mass | 365.4 (anhydrous) \\
| | 419.4 (trihydrate form) |

**Potassium clavulanate**
Excipients: Xanthan gum, hydroxy propyl methyl cellulose E-5, colloidal anhydrous silica, succinic acid, silicon dioxide, flavour raspberry dry powder, flavour orange dry powder PFW, flavour orange dry powder DRAGACO, flavour golden syrup dry powder, aspartame.

8. PHARMACEUTICAL PARTICULARS

8.1. Incompatibilities

No incompatibilities have been identified

8.2. Shelf Life

The expiry date is indicated on the label and packaging.

8.3. Packaging Information

Bottle in a carton with or without vial containing Sterile Purified Water for reconstitution.

8.4. Storage and Handling Information

Unopened container: Store in a well closed container at a temperature not exceeding 25°C, protected from moisture.

Do not use the product if seal is missing or not intact.

Reconstituted suspensions: should be stored in a refrigerator (2°-8°C) and used within seven days. Do not freeze.

When reconstituted, an off-white suspension is formed.

Keep out of reach of children.

At time of use, the dry powder should be reconstituted to form an oral suspension.

Direction for Preparation

For packs without water for reconstitution-
Shake the bottle to loosen powder. Then to make up to 30 mL add boiled and cooled water to 3/4th of fill-mark on bottle. Replace the cap and shake the bottle until all of the powder is suspended. Add more water until the level of the fill line is attained and shake again.

When first reconstituted, allow to stand for 5 minutes to ensure full dispersion.

After reconstitution keep in a refrigerator when not in use.
Use reconstituted suspension within 7 days.

For packs with water for reconstitution-

Shake the bottle to loosen powder. Then to make up to 30 mL, add Sterile Purified Water provided with the bottle of AUGMENTIN DDS to 3/4 of fill-mark on bottle. Replace the cap and shake the bottle until all the powder is suspended. Add more Sterile Purified Water until the level of the fill line is attained and shake again. After reconstitution, close the bottle tightly and immediately keep in a refrigerator when not in use. Use reconstituted suspension within 7 days.

Do not use if powder / reconstituted solution turns pale yellow to brown colour.

For paediatric use.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients and/or their patients’ parents about the Special Warnings and Precautions for Use, Drug Interactions, Undesirable Effects, and any relevant contra-indications of AUGMENTIN DDS. Patients 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

24 October 2019

Trade marks are owned by or licensed to the GSK group of companies.

Version: AUG-DDS/PI/IN/2019/02

Adapted from Augmentin Oral GDS version 26 and Augmentin Paediatric Syrup IPI version 14 dated 13 June 2019.