Clean Professional Information for medicines for human use

Indo Amoxycillin 250 and Indo Amoxycillin-500 (Capsules)

SCHEDULING STATUS S4

1 NAME OF THE MEDICINE

Indo Amoxycillin 250 (250 mg Capsules)

Indo Amoxycillin-500 (500 mg Capsules)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

INDO AMOXYCILLIN 250: Each capsule contains amoxicillin trihydrate equivalent to 250 mg amoxicillin.

INDO AMOXYCILLIN-500: Each capsule contains amoxicillin trihydrate equivalent to 500 mg amoxicillin.

Sugar free.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsules

INDO AMOXYCILLIN 250 - Hard gelatin capsules, size “2” Maroon cap /yellow coloured body, printed with “AMOXY 250” in black ink on the body and cap in a circular manner, containing white to off white granular powder.

INDO AMOXYCILLIN-500 - Hard gelatin capsules, size “0” Maroon cap /yellow coloured body, printed with “AMOXY 500” in black ink on the body and cap in a circular manner, containing white to off white granular powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

INDO AMOXYCILLIN formulation is indicated for the treatment of mild to moderately severe infections caused by susceptible organisms:

- Upper respiratory tract infections such as sinusitis, otitis media, tonsillitis.
- Lower respiratory tract infections such as bronchitis, lobar and bronchopneumonia.
- Gastro-intestinal tract infections such as typhoid fever.
- Other infections including Borreliosis (Lyme disease).
- In the following infections, amoxicillin therapy should be initiated only if there is microbiological evidence that the causative organism is sensitive to amoxicillin:
  Skin and soft tissue infections.
  Urinary tract infections: cystitis, urethritis, pyelonephritis, bacteriuria in pregnancy.
- “As part of combination therapy in established *Helicobacter pylori* infection, associated with duodenal ulceration”.
- Prophylaxis of endocarditis.
- Gonorrhoea

4.2 Posology and method of administration

Posology

The total daily dose as below is administered in divided doses. The most common regimen is 8 hourly.

Treatment should be continued for 48 to 72 hours beyond the time that a clinical response has been obtained. It is recommended that at least 10 days treatment be given for any infection caused by beta-haemolytic streptococci to prevent the occurrence of acute rheumatic fever or glomerulonephritis.

Adults and children over 40 kg:

Total daily dosage of 750 mg to 3 g administered in divided doses.

Maximum recommended dose: 6 g/day in divided doses.

Respiratory tract infections: 500 mg administered 8 hourly.

Lyme disease: 4 g/day in isolated erythema chronicum migrans and 6 g/day in the case of generalised manifestations, both for a minimum of 12 days.

Gonorrhoea: 3 g with 1 g probenecid.

Eradication of Helicobacter pylori: 750 mg – 1 g in combination treatment given 12 hourly for the eradication of established H pylori infection associated with duodenal ulceration for 7 days.

Children under 40 kg:

20-50 mg/kg/day in divided doses. Maximum recommended dose: 150 mg/kg/day in divided doses.

Lyme disease: 25-50 mg/kg/day in isolated erythema chronicum migrans and 100 mg/kg/day in the case of generalised manifestations, both for a minimum of 12 days.

Elderly:

No adjustment needed: as for adults unless there is evidence of severe renal impairment (see below).

Renal impairment:

Glomerular filtration rate > 30 ml/min: No adjustment needed.

Glomerular filtration rate 10-30 ml/min: Maximum 500 mg every 12 hours.

Glomerular filtration rate < 10 ml/min: Maximum 500 mg daily.

In patients receiving peritoneal dialysis: Maximum 500 mg daily.

Prophylaxis of endocarditis:

Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month or is allergic to penicillin.

Method of administration

For oral use.

The absorption of INDO AMOXYCILLIN is not affected significantly when taken with food. INDO AMOXYCILLIN may, therefore, be taken with meals.

4.3 Contraindications

- Hypersensitivity to penicillins or to cephalosporins or to any of the excipients listed in see section 6.1.
- Amoxicillin as contained in INDO AMOXYCILLIN is penicillin and should not be given to patients with a history of hypersensitivity to β-lactam antibiotics (e.g. carbapenem or

monobactam). Potential cross allergy to other beta-lactams such as cephalosporins should be taken into account.

4.4 Special warnings and precautions for use

Hypersensitivity reactions:

- Serious and occasional fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy.
- Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction (see section 4.8).
- Before initiating therapy with INDO AMOXYCILLIN, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens (see sections 4.3).

  Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity, who have experienced severe reactions when treated with cephalosporins.
- If an allergic reaction occurs, INDO AMOXYCILLIN should be discontinued and the appropriate therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, may also be required.
- Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin/clavulanate (see section 4.8). DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after intake of amoxicillin) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise

abdominal pain, diarrhoea, hypotension or leucocytosis with neutrophilia. There have been severe cases including progression to shock.

Non-susceptible microorganisms

- The use of INDO AMOXYCILLIN may lead to the selection of resistant strains of organisms and sensitivity testing should, therefore, be carried out whenever possible, to demonstrate the appropriateness of therapy.
- INDO AMOXYCILLIN is not suitable for the treatment of some types of infection unless the pathogen is already documented and known to be susceptible or there is a very high likelihood that the pathogen would be suitable for treatment with INDO AMOXYCILLIN. This particularly applies when considering the treatment of patients with urinary tract infections and severe infections of the ear, nose and throat.
- Since INDO AMOXYCILLIN contains amoxycillin, an aminopenicillin, it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause in infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxycillin is used (see sub-header 'Skin reactions').

There is insufficient evidence at present to show that INDO AMOXYCILLIN penetrates into the cerebrospinal fluid in therapeutic quantities and it should, therefore, not be used in the treatment of cerebrospinal infections.

Convulsions

Convulsions may occur in patients with impaired renal function or in those receiving high doses or in patients with predisposing factors (e.g. history of seizures, treated epilepsy or meningeal disorders (see section 4.8).

Impaired renal function:

In patients with moderate or severe renal impairment, INDO AMOXYCILLIN dosage should be adjusted (see section 4.2).

Skin reactions

INDO AMOXYCILLIN 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.

The occurrence at the treatment initiation of a feverish generalised erythema associated with pustula may be a symptom of acute generalised exanthemous pustulosis (AEGP). This reaction requires INDO AMOXYCILLIN discontinuation and contraindicates any subsequent administration.

Lymphatic leukaemia:

INDO AMOXYCILLIN should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxycillin induced skin rashes.

Jarisch-Herxheimer reaction

Caution is needed when administering amoxicillin to patients with syphilis, as the Jarisch-Herxheimer reaction may occur in these patients.

The Jarisch-Herxheimer reaction has been reported following amoxicillin treatment of Lyme disease (see section 4.8). It results directly from the bactericidal activity of amoxicillin on the causative bacteria of Lyme disease, the spirochaete *Borrelia burgdorferi*. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease.

Overgrowth of non-susceptible microorganisms

- Prolonged use may result in overgrowth of non-susceptible organisms.
- Antibiotic associated *Pseudomembranous enterocolitis* has been reported.

  The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with INDO AMOXYCILLIN use (this may occur up to several weeks after cessation of INDO AMOXYCILLIN therapy). If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment with INDO AMOXYCILLIN should be discontinued immediately.
- Anti-peristaltic medicines are contraindicated in this situation.

Anticoagulants

Prolongation of prothrombin time has been reported rarely in patients receiving INDO AMOXYCILLIN. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.

Prolonged therapy

Periodic assessment of organ function, including renal, hepatic and haematopoietic functions, is advisable during prolonged therapy.

- The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, the agent should be discontinued and/or appropriate therapy instituted.

Allopurinol:

INDO AMOXYCILLIN should preferably not be used in patients treated with allopurinol since they are especially susceptible to ampicillin-induced skin rashes (see section 4.5).

Crystalluria

In patients with reduced urine output, crystalluria (including acute renal injury) has been observed. The presence of high urinary concentrations of INDO AMOXYCILLIN can cause precipitation of the product in urinary catheters. Therefore, catheters should be visually inspected at intervals. When high doses are administered, adequate fluid intake and urinary output must be maintained (see section 4.8 and 4.9).

Impaired hepatic function:

- Changes in liver function tests have been observed in some patients receiving INDO AMOXYCILLIN.
- INDO AMOXYCILLIN should be used with care in patients with evidence of severe hepatic dysfunction.
- Transient hepatitis and cholestatic jaundice have been reported.

Use in lactation:

INDO AMOXYCILLIN is excreted in the milk. Therefore, caution should be exercised when INDO AMOXYCILLIN is administered to lactating women (see section 4.6).

Interference with diagnostic tests

Elevated serum and urinary levels of amoxicillin are likely to affect certain laboratory tests. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used.

The presence of amoxicillin may distort assay results for oestriol in pregnant women.

Oral hormonal contraceptives:

- INDO AMOXYCILLIN may reduce the efficacy of oral contraceptives and patients should be warned accordingly (see section 4.5).

Important information about excipients of INDO AMOXYCILLIN:

INDO AMOXYCILLIN 250 and INDO AMOXYCILLIN 500 contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicines and other forms of interaction

Due to amoxicillin’s effect on intestinal flora, the absorption of other medicines may be affected.

Probenecid:

- Probenecid decreases the renal tubular secretion of INDO AMOXYCILLIN.
- Concurrent use with INDO AMOXYCILLIN may result in increased and prolonged blood concentrations of INDO AMOXYCILLIN.

Oral hormonal contraceptives:

INDO AMOXYCILLIN may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Allopurinol:

The concomitant administration of allopurinol and ampicillin substantially increases the incidence of skin rashes in patients receiving both agents as compared to patients receiving ampicillin alone (see section 4.4). It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients.

Digoxin:

- The absorption of concurrently administered digoxin may be increased during treatment with INDO AMOXYCILLIN.

Anticoagulants:

- Concomitant administration of INDO AMOXYCILLIN and anticoagulants e.g. coumarin may prolong the bleeding time.
- A dose adjustment of anticoagulants may be necessary (see section 4.4). If coadministration is necessary, the prothrombin time or internationally normalised ratio should be carefully monitored with the addition or withdrawal of INDO AMOXYCILLIN.

Tetracyclines

Tetracyclines and other bacteriostatic medicines may interfere with the bactericidal effects of INDO AMOXYCILLIN.

Methotrexate

- Interaction between INDO AMOXYCILLIN and methotrexate leading to methotrexate toxicity has been reported.
- Serum methotrexate levels should be closely monitored in patients who receive INDO AMOXYCILLIN and methotrexate simultaneously (see section 4.4). INDO AMOXYCILLIN decreases the renal clearance of methotrexate, probably by competition at the common tubular secretion system.

Other forms of interactions:

- Forced diuresis leads to a reduction in blood concentrations by increased elimination of INDO AMOXYCILLIN.
- INDO AMOXYCILLIN may interfere with protein testing when colorimetric methods are used.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/ Contraception in males and females

INDO AMOXYCILLIN may reduce the efficacy of oral contraceptives and patients should be warned accordingly (see section 4.5).

Pregnancy

The safety of INDO AMOXYCILLIN in pregnancy has not been established.

Breastfeeding

INDO AMOXYCILLIN is distributed into breast milk and should be used with caution when administered to lactating women. Although significant problems in humans have not been documented, the use of INDO AMOXYCILLIN by lactating women may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

4.7 Effects on ability to drive and use machines

INDO AMOXYCILLIN may cause allergic reactions, dizziness or convulsions and may thus have an effect on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision (see section 4.8).

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse side effects are diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes.

Tabulated summary of adverse reactions

MedDRA system organ class	**Frequency**	**Adverse reactions**
Infections and infestations	Less frequent	*Mucocutaneous candidiasis*
Blood and the lymphatic system disorders [3]:	Frequency unknown	Prolongation of bleeding time and prothrombin time (see section 4.4)[6]. Haemolytic anaemia, reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia, reversible leucopenia and agranulocytosis.
Immune system disorders (see section 4.3 & 4.4) [8]:	Less frequent	Serum sickness-like syndrome, Hypersensitivity vasculitis, Anaphylaxis Angioneurotic oedema
Nervous System disorders:	Less frequent	Reversible hyperactivity, hyperkinesia dizziness, headache and convulsions. (see section 4.4)[9]
	Frequency unknown	Aseptic meningitis
Cardiac disorders:	Frequency unknown	Kounis syndrome (see section 4.4)

Gastrointestinal disorders [1]:	Less frequent	Diarrhoea, nausea, vomiting, Gastritis Stomatitis, Glossitis, Enterocolitis Black hairy tongue, Antibiotic-associated colitis including pseudomembranous colitis and haemorrhagic colitis (see section 4.4), Tooth discolouration[7]
	Frequency unknown	Drug-induced enterocolitis syndrome (DIES) (see section 4.4)
Hepatobiliary disorders [4]:	Less frequent	Hepatitis and cholestatic jaundice have been reported.
	Frequency unknown	Rises in AST and/or ALT [5]
Skin and subcutaneous tissue disorders [2]:	Less frequent	Skin rash, Erythematous maculopapular rash Pruritus and urticaria, erythema multiforme, bullous exfoliative dermatitis and toxic epidermal necrolysis. Stevens-Johnson Syndrome, Acute generalised pustulosis, Lyell's syndrome Acute generalised exanthemous pustulosis (AGEP) (see section 4.4),

		Drug reaction with eosinophilia and systemic symptoms (DRESS), Jarisch-Herxheimer reaction (see section 4.4)
	Frequency unknown	Linear IgA disease
Renal and urinary disorders:	Less frequent	interstitial nephritis
	Frequency unknown	Crystalluria (including acute renal injury) (see section 4.9)

[1] If gastrointestinal disorders are evident, they may be reduced by taking INDO AMOXYCILLIN at the start of a meal.

[2] Whenever such skin and subcutaneous tissue disorders occur, INDO AMOXYCILLIN should be discontinued.

[3] Haematological effects are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1% of patients treated with INDO AMOXYCILLIN.

[4] The hepatobiliary disorders may be severe, and occur predominantly in adult or elderly patients. 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.

The hepatic effects are usually reversible. However, in extremely rare circumstances, death has been reported. These have almost always been cases associated with serious underlying disease or concomitant medication.

[5] A moderate rise in Aspartate Transaminase (AST) or SGOT and/or Alanine Tranfersae transaminase (ALT) or SGPT has been noted in patients treated with INDO AMOXYCILLIN, but the significance of these findings is unknown.

[6] Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantl

[7] It can be removed by brushing.

[8] Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin. In the event of an anaphylactic reaction, immediate treatment with adrenalin, oxygen, corticosteroids and antihistamines should be initiated.

[9] Convulsions may occur with impaired renal function or in those receiving high doses.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

Symptoms:

Oral administration can cause gastro-intestinal symptoms such as transient diarrhoea, nausea and colic which are dose-related and a result of local irritation and not toxicity.

Treatment

- If encountered, gastro-intestinal symptoms and disturbances of the fluid and electrolyte balance may be evident.
- They may be treated symptomatically and supportive with attention to the water/electrolyte balance.
- In the absence of an adequate fluid intake and urinary output, crystalluria, in some cases leading to renal failure, is a possibility.
- Amoxicillin may be removed from the circulation by haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 20.1.2 Penicillins

Pharmacotherapeutic group: penicillins with extended spectrum; ATC Code: J01CA04

(a) Bacteriology

(i) Spectrum:

Amoxicillin is a semisynthetic beta-lactamase-susceptible penicillin, which has *in vitro* bactericidal activity against broad spectrum of non beta-lactamase-producing Gram-positive and Gram-negative organisms. The spectrum of activity does not include those organisms that produce beta lactamases, namely resistant staphylococci, and all strains of *Pseudomonas, Klebsiella and Enterobacter*.

The following organisms are generally sensitive to the bactericidal action of the amoxicillin *in vitro*. *In vitro* sensitivity does not mean *in vivo* efficacy [(*) denotes sensitivity tests must be performed].

Gram-positive bacteria:

*Staphylococcus aureus (penicillin-sensitive)**

Streptococcus pyogenes

*Streptococcus viridans**

*Streptococcus faecalis**

*Streptococcus pneumoniae**

*Corynebacterium species**

*Clostridium species**

*Bacillus anthracis**

Listeria monocytogenes

Gram-negative bacteria:

*Neisseria gonorrhoeae**

Neisseria meningitidis (except the carrier state)*

*Haemophilus influenzae**

Bordetella pertussis

*Escherichia coli**

*Salmonella species**

*Shigella species**

*Proteus mirabilis**

*Pasteurella multocida**

Helicobacter pylori

Leptospira species

*Fusabacterium species**

5.2 Pharmacokinetic properties:

(b) Absorption:

Amoxicillin is rapidly and well absorbed orally. A single 250 mg oral dose achieves an average peak serum level virtually equal to that achieved by IM injection viz. 5,38 µg/ml oral and 5,6 µg/ml IM. The peak serum level is achieved within 1,5 - 2 hours after oral and 15 minutes after IM or IV (18,2 µg/ml) administration.

After oral administration, there is no significant difference between the peak serum levels in fasting and non-fasting subjects. The presence of food does not interfere with the absorption of INDO AMOXYCILLIN. INDO AMOXYCILLIN may, therefore, be taken with meals. There is a linear/dose response in peak serum levels after both oral and parenteral administration.

(c) Distribution:

Approximately 18% of the total plasma amoxicillin content is protein bound.

Amoxicillin diffuses readily into most body tissues with the exception of the brain and spinal fluid.

Inflammation generally increases the permeability of the meninges to penicillins and this may apply to amoxicillin.

(i) Sputum:

The concentration of amoxicillin in sputum does not decrease as occurs with ampicillin as purulence subsides.

(ii) Bile:

INDO AMOXYCILLIN is present in bile obtained from a common bile duct drain of a healthy gallbladder, however, biliary levels are lower when the gallbladder is diseased and absent in the presence of biliary tract obstruction.

(iii) Urine:

The average concentration of INDO AMOXYCILLIN in urine collected during the first six hours after 250 mg oral dose is 580 µg/ml.

(d) Excretion

The elimination half-life is approximately 1 hour. Amoxicillin is primarily excreted via the kidneys. Small amounts of the drug are also excreted in the faeces and bile. Amoxycillin crosses the placenta and is distributed into breast milk.

Approximately 60 % of an oral dose of amoxicillin is excreted unchanged in the active form into the urine within six hours. Approximately 70 % - 80 % of an intramuscular dose and 90 % of an intravenous dose is excreted unchanged in the active form, into the urine within 12 hours.

Probenecid

Even higher INDO AMOXYCILLIN serum levels may be achieved after oral administration to patients with normal renal function, by the simultaneous administration of a renal blocking

medicine such as probenecid. Probenecid should not be given in the presence of abnormal renal function. No data on the effect of probenecid on parenteral amoxicillin are yet available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content

Sodium Lauryl Sulphate

Purified Talc

Magnesium Stearate

Capsule shell

Cap:

Carmosine

Sunset Yellow

Indigo Carmine

Titanium Dioxide

Body:

Sunset Yellow

Iron Oxide Yellow

Titanium Dioxide

Shell Composition:

Water

Sodium Lauryl Sulphate

Gelatin

Methyl paraben (Preservative)

Propyl paraben (Preservative)

Printing ink Components

Black Iron Oxide

Shellac

Isopropyl Alcohol

Alcohol

Propylene Glycol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

INDO AMOXYCILLIN 250 – 36 months

INDO AMOXYCILLIN-500 – 36 months

6.4 Special precautions for storage

Store tightly closed in a dry place at or below 30 °C and protect from light.

Keep the blisters in the carton until required for use.

Keep out of reach of children.

6.5 Nature and contents of container

INDO AMOXYCILLIN 250 capsules:

Silver aluminium foil/clear, transparent PVC foil blisters in strips of 10 capsules, packed in 20,

100 or 500 capsules per carton.

White round HDPE container with cap containing 100 or 500 capsules.

White polyethylene capsule envelopes (Patient Ready Packs) of different pack sizes.

INDO AMOXYCILLIN-500 capsules:

Silver aluminium foil/clear, transparent PVC foil blisters in strips of 10 capsules, packed in 20, 100 or 500 capsules per carton.

White round HDPE container with cap containing 100 or 500 capsules.

White polyethylene capsule envelopes (Patient Ready Packs) of different pack sizes.

6.6 Special precautions for disposal and other handling

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Unimed Healthcare (Pty) Ltd

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Anchorville

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8 REGISTRATION NUMBERS

INDO AMOXYCILLIN 250: A40/20.1.2/0329

INDO AMOXYCILLIN-500: A40/20.1.2/0330

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORIZATION

Date of registration: 02 February 2007– INDO AMOXYCILLIN 250

Date of registration: 02 February 2007– INDO AMOXYCILLIN-500

10 DATE OF REVISION OF THE TEXT

29 November 2024