1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product:

NOMEXICLAV 625 TABLETS

1.1 Name of the medicinal product:

Amoxicillin and Potassium Clavulanate Tablets BP

1.2 Strength:

Each film coated tablet contains:

Amoxicillin Trihydrate BP

equivalent to Amoxicillin: 500 mg

Potassium Clavulanate BP

(As diluted Potassium Clavulanate BP) equivalent to Clavulanic Acid: 125 mg

Excipients: q.s.

Colour: Titanium Dioxide BP

1.3 Pharmaceutical form:

Tablet; Oral use

2. Qualitative and quantitative composition

Each film coated tablet contains:

Amoxicillin Trihydrate BP

equivalent to Amoxicillin: 500 mg

Potassium Clavulanate BP

(As diluted Potassium Clavulanate BP) equivalent to Clavulanic Acid: 125 mg

Excipients: q.s.

Colour: Titanium Dioxide BP

3. Pharmaceutical form

Tablet; Oral use

4. Clinical particulars:

4.1 Therapeutic indications:

Amoxicillin and Potassium Clavulanate Tablets are indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in panicular osteomyelitis.

4.2 Posology and method of administration

Route of administration: Oral Adults and children ≥ 40 kg

One 500 mg/125 mg dose taken three times a day.

Children < 40 kg

20 mg/5 mg/kg/day to 60 mg/15 mg/kg/day given in three divided doses.

No clinical data are available on doses of amoxicillin/clavulanic acid 4:1 formulation higher than 40 mg/ 10mg/kg per day in children under 2 years.

Elderly

No dose adjustment is considered necessary

METHOD OF ADMINISTRATION:

The tablets are meant for oral use.

Administer at the stan of a meal to minimize potential gastrointestinal intolerance and optimize absorption of amoxicillin/clavulanic acid.

4.3 Contraindications

Amoxicillin is contra-indicated in patients with hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.

It is also contraindicated in patients with a previous history of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. cephalosporin, carbapenem or monobactam). it is also contraindicated in patients with a previous history of jaundice/hepatic impairment associated with amoxicillin and potassium clavulanate.

4.4 Special warnings and precautions for use

Concerns related to adverse elects:

• Anaphylactoid/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy, especially with a history of beta-lactam hypersensitivity, history of sensitivity to multiple allergens, or previous IgE-mediated reactions (eg, anaphylaxis, angioedema, unicaria). Use with caution in asthmatic patients. Low incidence of cross-allergy with cephalosporins exists.

• Diarrhea Incidence of diarrhea is higher than with amoxicillin alone.

• Hepatic effects: Although rare, hepatic dysfunction is more common in elderly and/or males, and occurs more frequently with prolonged treatment, and may occur after therapy is complete.

• Superinfection: Prolonged use may result in fungal or bacterial superinfection, including C. difficile-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed ≥2 months postantibiotic treatment.

• Hepatic impairment: Use with caution in patients with hepatic impairment.

• Infectious mononucleosis: A high percentage of patients with infectious mononucleosis have developed rash during therapy; ampicillin-class antibiotics not recommended in these patients.

• Renal impairment: Use with caution in patients with renal impairment; dosage adjustment recommended.

Dosage forms specific issues:

• Clavulanic acid content: Due to differing content of clavulanic acid, not all formulations are interchangeable.

• Phenylalanine: Some products contain phenylalanine

GENERAL PRECAUTIONS:

Mile amoxicillin and potassium clavulanate possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy.

A high percentage of patients with mononucleosis who receive ampicillin develop an erythematous skin rash. Thus, ampicillin-class antibiotics should not be administered to patients with mononucleosis.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

Prescribing amoxicillin and potassium clavulanate in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

4.5 Interaction with other medicinal products and other forms of interaction

Allopurinol May enhance the potential for allergic or hypersensitivity reactions to

Risk C: Monitor therapy.

Fusidic Acid: May diminish the therapeutic elect of Penicillins.

Risk D: Consider therapy modification.

Methotrexate: Penicillins may decrease the excretion of Methotrexate.

Risk C: Monitor therapy.

Mycophenolate: Penicillins may decrease serum concentrations of the active metabolite(s) of Mycophenolate. This elect appears to be the result of impaired enterohepatic recirculation.

Risk C: Monitor therapy

Tetracycline Derivatives: May diminish the therapeutic effect of Penicillins.

Risk D: Consider therapy modification.

Typhoid Vaccine: Antibiotics may diminish the therapeutic effect of Typhoid Vaccine. Only the live attenuated Ty21a strain is affected.

Risk D: Consider therapy modification.

Uricosuric Agents: May decrease the excretion of Penicillins.

Risk C: Monitor therapy.

4.6 Pregnancy and lactation

Reproduction studies in animals (mice and rats) with orally and parenterally administered Amoxicillin and Potassium Clavulanate Tablets 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 Amoxicillin and Potassium Clavulanate Tablets 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. Amoxicillin and Potassium Clavulanate Tablets 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:

Amoxicillin and clavulanate potassium are generally well tolerated. The majority of side elects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug-related side effects. The most frequently reported adverse elects were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). The overall incidence of side effects, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported reactions include: Abdominal discomfort, flatulence, and headache.

The following adverse reactions have been reposed for ampicillin-class antibiotics:

Gastrointestinal: Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black ”hairy" tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic / pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Hypersensitivity Reactions: Skin rashes, pruritus, urticaria, angioedema, serum sickness like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), erythema multiforme (rarely Stevens-Johnson syndrome), acute generalized

exanthematous pustulosis, hypersensitivity vasculitis, and an occasional case of exfoliative dermatitis (including toxic epidermal necrolysis) have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with oral penicillin.

Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted in patients treated with ampicillin-class antibiotics, but the significance of these findings is unknown. Hepatic dysfunction, including hepatitis and cholestatic jaundice, increases in serum transaminases (AST and/or ALT}, serum bilirubin and/or alkaline phosphatase, has been infrequently reported with amoxicillin and potassium clavulanate. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of predominantly cholestatic, hepatocellular, or mixed cholestatic-hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks ater therapy has been discontinued. The hepatic dysfunction, which may be severe, is usually reversible. On rare occasions, deaths have been reported (less than 1 death reported per estimated 4 million prescriptions worldwide). These have generally been cases associated with serious underlying diseases or concomitant medications.

Renal: Interstitial nephritis and hematuria have been reported rarely. Crystalluria has also been reposed.

Hemic and Lymphatic System: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reposed during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1°â of the patients treated with amoxicillin and potassium clavulanate. There have been reports of increased prothrombin time in patients receiving amoxicillin and potassium clavulanate and anticoagulant therapy concomitantly.

Central Nervous system: Agitation, anxiety, behavioral changes, confusion, convulsions, dizziness, insomnia, and reversible hyperactivity have been reported rarely.

Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been rarely reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

4.9 Overdose:

Following overdosage, patients have experienced primarily gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhea. Rash, hyperactivity, or drowsiness have also been observed in a small number of patients.

In the case of overdosage, discontinue amoxicillin / clavulanate potassium, treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. A prospective study of 51 pediatric patients at a poison center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.

5. Pharmacological properties:

5.1 Pharmacodynamics properties:

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in Amoxicillin and Potassium Clavulanate Tablets anticipates this defence mechanism by blocking the β-lactamase enzymes, thus rendering the organisms susceptible to amoxicillin's rapid bactericidal effect at concentrations readily attainable in the body. Clavulanate by itself has little antibacterial activity; however, in association with amoxicillin as Amoxicillin and Potassium Clavulanate Tablets it produces an antibiotic agent of broad spectrum with wide application in hospital and general practice. Amoxicillin and Potassium Clavulanate Tablets is bactericidal to a wide range of organisms including:

Gram-positive

Aerobes: Enterococcus faecalis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus viridans, *Staphylococcus aureus, *coagulase negative staphylococci (including Staphylococcus epidermidis), Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.

Anaerobes: Clostridium species, Peptococcus species, Peptostreptococcus.

Gram-negative

Aerobes: *Haemophilus influenzae, *Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella species, *Moraxella catarrhalis, *Salmonella species, *Shigella species, Bordetella pertussis, Brucella species, *Neisseria gonorrhoeae, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida. Anaerobes: *Bacteroides spp. including B. fragilis.

* including β-lactamase producing strains resistant to ampicillin and amoxicillin

5.2 Pharmacokinetic Properties

The pharmacokinetics of the two components of Amoxicillin and Potassium Clavulanate Tablets are closely matched. Peak serum levels of both occur about 1 hour after oral administration. Absorption of Amoxicillin and Potassium Clavulanate Tablets is optimised at the start of a meal. Doubling the dosage of Amoxicillin and Potassium Clavulanate Tablets approximately doubles the serum levels achieved. Both clavulanate and amoxicillin have low levels of serum binding; about 70% remains free in the serum.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

Repeat dose toxicity studies performed in dogs with amoxicillin/clavulanic acid demonstrate gastric irritancy and vomiting, and discoloured tongue.

Carcinogenicity studies have not been conducted with amoxicillin/clavulanic acid or its components.

6. Pharmaceutical particulars

6.1 List of excipients

NOMEXICLAV 625 TABLETS contain the following inactive ingredients: Microcrystalline cellulose BP, Sodium Starch Glycolate BP, Magnesium Stearate BP, Hydrophobic Colloidal anhydrous silica BP, Polacrilin potassium (Kyron T 314) USP, Sodium Lauryl sulfate BP, Insta coat Transparent IC-S-344 In-house, Cross carmellose Sodium BP, Isopropyl Alcohol BP, Dichloromethane BP, Insta Moist Transparent IC-MS-218 (White) In-house and Titanium Dioxide BP as excipients.

6.2 Incompatibilities

None

6.3 Shelf life

24 Months (2 Years) from date of manufacturing

6.4 Special precautions for storage

Store below 25°C. Protect from light and moisture.

Keep medicine out of reach of children.

6.5 Nature and contents of container

Alu Alu blister of 7 tablets. Such 2 blisters in a printed carton along with pack insert.

6.6 Special precautions for disposal:

None

7. Registrant:

MARKETING AUTHORISATION HOLDER

NOMEDI PHARMACEUTICALS LTD

387, Agege Motor Road, Mushin,

P. O. Box 11623,

Ikeja, Lagos - Nigeria.

Phone: +2348027000578

E-mail: cliffordnzimako@yahoo.com

8. MANUFACTURER

CORAL LABORATORIES LTD.

Plot No. 27-28, Pharmacity, Selaqui (Dehradun), Uttarakhand – 248 011. INDIA.

Telephone: 91-22-22873694, 2287 3635, 2287 3745, 2287 3698

Telefax: 91-22-22875757

Email: reg@corallab.com, exports@corallab.com

9. Date of revision of the text: NA

2.16.2 PATIENT INFORMATION LEAFLET

Enclosed

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

NOMEXICLAV 625 TABLETS (Amoxicillin and Potassium Clavulanate Tablets BP)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor, health care provider or pharmacist.

• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. WHAT NOMEXICLAV 625 TABLETS IS AND WHAT IT IS USED FOR

Amoxicillin/clavulanic acid is an antibiotic medication used for the treatment of a number of bacterial infections.

Amoxicillin and Potassium Clavulanate Tablets are indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and sot tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.

- Bone and joint infections, in panicular osteomyelitis.

For complete cure it is important that you complete the prescribed dose as advised by your doctor, pharmacist or health care provider.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NOMEXICLAV 625 TABLETS

Do not take NOMEXICLAV 625 TABLETS –

if you are allergic to or any of the other ingredients of NOMEXICLAV 625 TABLETS (see section 6, What NOMEXICLAV 625 TABLETS contains), -

If you have any doubt, it is essential to ask the advice of your doctor, pharmacist or health care provider.

Warnings and precautions

Concerns related to adverse elects:

• Anaphylactoid/hypersensitivity reactions: Serious and occasionally severe or fatal hypersensitivity (anaphylactoid) reactions have been reported in patients on penicillin therapy, especially with a history of beta-lactam hypersensitivity, history of sensitivity to multiple allergens, or previous IgE-mediated reactions (eg, anaphylaxis, angioedema, unicaria). Use with caution in asthmatic patients. Low incidence of cross-allergy with cephalosporins exists.

• Diarrhea Incidence of diarrhea is higher than with amoxicillin alone.

• Hepatic effects: Although rare, hepatic dysfunction is more common in elderly and/or males, and occurs more frequently with prolonged treatment, and may occur after therapy is complete.

• Superinfection: Prolonged use may result in fungal or bacterial superinfection, including C. difficile-associated diarrhea (CDAD) and pseudomembranous colitis; CDAD has been observed ≥2 months postantibiotic treatment.

• Hepatic impairment: Use with caution in patients with hepatic impairment.

• Infectious mononucleosis: A high percentage of patients with infectious mononucleosis have developed rash during therapy; ampicillin-class antibiotics not recommended in these patients.

• Renal impairment: Use with caution in patients with renal impairment; dosage adjustment recommended.

Dosage forms specific issues:

• Clavulanic acid content: Due to differing content of clavulanic acid, not all formulations are interchangeable.

• Phenylalanine: Some products contain phenylalanine

GENERAL PRECAUTIONS:

Mile amoxicillin and potassium clavulanate possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy.

A high percentage of patients with mononucleosis who receive ampicillin develop an erythematous skin rash. Thus, ampicillin-class antibiotics should not be administered to patients with mononucleosis.

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Pseudomonas or Candida), the drug should be discontinued and/or appropriate therapy instituted.

Prescribing amoxicillin and potassium clavulanate in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Pregnancy and breast-feeding

Reproduction studies in animals (mice and rats) with orally and parenterally administered Amoxicillin and Potassium Clavulanate Tablets 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 Amoxicillin and Potassium Clavulanate Tablets 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. Amoxicillin and Potassium Clavulanate Tablets 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

Driving and using machines

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

3. HOW TO TAKE NOMEXICLAV 625 TABLETS

Always take NOMEXICLAV 625 TABLETS exactly as your doctor has told you. You should check with your doctor, pharmacist or health care provider if you are not sure.

If you take more NOMEXICLAV 625 TABLETS than you should

If you accidentally take a lot more tablets than the doctor prescribed, contact a doctor or the nearest hospital emergency department immediately, or make sure that someone else contacts them for you.

If any of these symptoms occur, **stop the treatment and consult a doctor immediately.**

If you forget to take NOMEXICLAV 625 TABLETS

Try to make sure that you do not miss any dose. However, if you do forget a dose, take the missed dose as soon as you realise that you have forgotten it. Then take the next dose after the prescribed interval. **Do not take a double dose to make up for a forgotten tablet.**

If you stop taking NOMEXICLAV 625 TABLETS

To be effective the medicine must be taken regularly at the dose prescribed and for as long as your doctor has advised.

If you have any further questions on the use of this product, ask your doctor, pharmacist or health care provider.

4. POSSIBLE SIDE EFFECTS

Amoxicillin and clavulanate potassium are generally well tolerated. The majority of side elects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug-related side effects. The most frequently reported adverse elects were diarrhea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). The overall incidence of side effects, and in particular diarrhea, increased with the higher recommended dose. Other less frequently reported reactions include: Abdominal discomfort, flatulence, and headache.

The following adverse reactions have been reposed for ampicillin-class antibiotics:

Gastrointestinal: Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black ”hairy" tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic / pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Hypersensitivity Reactions: Skin rashes, pruritus, urticaria, angioedema, serum sickness like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), erythema multiforme (rarely Stevens-Johnson syndrome), acute generalized exanthematous pustulosis, hypersensitivity vasculitis, and an occasional case of exfoliative dermatitis (including toxic epidermal necrolysis) have been reported. These reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. whenever such reactions occur, the drug should be discontinued, unless the opinion of the physician dictates otherwise. Serious and occasional fatal hypersensitivity (anaphylactic) reactions can occur with oral penicillin.

Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted in patients treated with ampicillin-class antibiotics, but the significance of these findings is unknown. Hepatic dysfunction, including hepatitis and cholestatic jaundice, increases in serum transaminases (AST and/or ALT}, serum bilirubin and/or alkaline phosphatase, has been infrequently reported with amoxicillin and potassium clavulanate. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of predominantly cholestatic, hepatocellular, or mixed cholestatic-hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks ater therapy has been discontinued. The hepatic dysfunction, which may be severe, is usually reversible. On rare occasions, deaths have been reported (less than 1 death reported per estimated 4 million prescriptions worldwide). These have generally been cases associated with serious underlying diseases or concomitant medications.

Renal: Interstitial nephritis and hematuria have been reported rarely. Crystalluria has also been reposed.

Hemic and Lymphatic System: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reposed during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1°â of the patients treated with amoxicillin and potassium clavulanate. There have

been reports of increased prothrombin time in patients receiving amoxicillin and potassium clavulanate and anticoagulant therapy concomitantly.

Central Nervous system: Agitation, anxiety, behavioral changes, confusion, convulsions, dizziness, insomnia, and reversible hyperactivity have been reported rarely.

Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been rarely reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

5. HOW TO STORE MONOKIT

Keep this medicine out of the sight and reach of children. .

Store below 25°C. Protect from light and moisture.

Do not use **NOMEXICLAV 625 TABLETS** after the expiry date which is stated on the blister and the outer packaging after EXP. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What NOMEXICLAV 625 TABLETS contains

The active ingredients are Amoxicillin Trihydrate BP and Potassium Clavulanate BP

The other ingredients are:

Microcrystalline cellulose BP, Sodium Starch Glycolate BP, Magnesium Stearate BP, Hydrophobic Colloidal anhydrous silica BP, Polacrilin potassium (Kyron T 314) USP, Sodium Lauryl sulfate BP, Insta coat Transparent IC-S-344 In-house, Isopropyl Alcohol BP, Dichloromethane BP, Insta Moist Transparent IC-MS-218 (White) In-house, Cross carmelose sodium BP and Titanium Dioxide BP as excipients.

What NOMEXICLAV 625 TABLETS looks like and contents of the pack

Description: Off white oval shaped, biconvex film coated tablets

Carton containing;

7 Tablets in an Alu Alu blister,

Such 2 blisters are packed in printed carton along with pack insert.