Summary of products characteristics (SmPC):

1. Name of the Medicinal Product: AMOXIREN CAPSULES

Strength:

Each hard gelatin capsule contains Amoxicillin trihydrate BP equivalent to Amoxicillin 250mg

2. Qualitative and Quantitative composition:

Each capsule contains Amoxicillin trihydrate BP equivalent to Amoxicillin 250mg.

For the full list of excipients, See section 6.1

3.Pharmaceutical form: Capsules

Maroon coloured cap/ yellow coloured body '2' size hard gelatin capsules "AMOXY 250" imprinted on body, "Rene Rene" imprinted on cap with black ink contains off white granular powder.

4. Clinical particular's:

4.1 Therapeutic indication:

Amoxicillin is indicated in the treatment of a variety of infections due to susceptible organisms, including Respiratory tract infections, Ear Nose and Throat infections. Urinary tract infections, Gastro-intestinal infections, Gonorrhoea, Enteric infections, Meningitis, Septicemia, Biliary tract infections, infective Endocarditis, Skin and soft tissue infections, Peritonitis, syphilis and Dental abscess.

4.2 Posology and method of administration:

The usual adult oral dose is 250 - 500mg of the equivalent of anhydrous Amoxicillin three times daily depending on severity of infections. The recommended doses of Amoxicillin in specific diseases are as follows.

Typhoid and Paratyphoid:

Adult: 4g daily in divided doses for 14 to 21 days.

Children: 100mg/kg/day in divided doses for 14 to 21 days.

Typhoid carrier states:

3-4g daily in divided doses for minimum of 1 month.

Meningitis:

Adult: 150mg/kg/day in equally divided doses.

Children: 100-150mg/kg/day in equally divided doses

Respiratory tract infections: 3g twice in divided doses.

Uncomplicated Urinary Tract Infection: A single dose of 3g

Syphillis: A dose of 250mg every 6 hours. Duration of treatment varies from a period of 4 weeks upto 5 months according to the stage of the disease and the serological response obtained.

Gonorrhoea: The equivalent of 3g of anhydrous Amoxicillin administered simultaneously with 1g of Probenecid as a single dose.
Dental abscess: Two 3g doses at an interval of 8 hours.

Method of Administration: Oral route.

4.3 Contraindication:
Amoxiren (Amoxicillin) is contraindicated in patients with a history of allergic reactions of penicillins.

4.4 Special warning and precaution for use:
Amoxiren (Amoxicillin) should preferably not be given to patients with infectious mononuclecsis since they are especially susceptible to Amoxicillin - induced skin rashes, patients with lymphatic leukemia and patients with hyperuricaemia being treated with allopurinol may also be at increased risk of developing skin rashes. Amoxicillin may decrease the efficacy of oestrogen containing oral contraceptives and it may also affect the absorption of other drugs due to its effect on the gastrointestinal flora.

4.5 Interactions with other medicinal products and other forms of interactions:
Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with amoxicillin may result in increased and prolonged blood levels of amoxicillin.
In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption and reduce efficacy of combined oral contraceptives.
Concurrent administration of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.
In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.
It is recommended that when testing for the presence of glucose in urine during amoxicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

Additional information on special populations:
Not Applicable

Pediatric population:
Precaution should be taken in premature children and during the neonatal period: renal, hepatic and haematological functions should be monitored.

4.6 Fertility, pregnancy and lactation:

Pregnancy

Animal studies with amoxicillin have shown no teratogenic effects. Amoxicillin has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies. The product should only be used during pregnancy where potential benefits outweigh the potential risks associated with treatment.

Breastfeeding

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

4.7 Effects on ability to drive and use machines:

Amoxicillin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects:

The side effects occasionally associated with the preparations include; vomiting, nausea, diarrhea, rashes, pruritis, fever, urticaria, and pseudomembreneous colitis.

4.9 Overdose and Treatment:

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillincrystalluria, in some cases leading to renal failure, has been observed.
Amoxicillin may be removed from the circulation by haemodialysis.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Penicillins with extended spectrum; ATC code: J01CA04.

Amoxicillin is a semi-synthetic, broad-spectrum penicillin, which is acid-resistant and has a similar antibacterial spectrum to ampicillin. It is bactericidal for both gram-positive and gram-negative bacteria.

Amoxicillin is well absorbed by the oral route. Oral administration, usually at convenient t.d.s. dosage, produces high serum levels independent of the time at which the food is taken. It is rapidly bactericidal and possesses the safety profile of a penicillin.

The wide range of organisms sensitive to the bactericidal action of Amoxicillin includes:

Gram-positive	Gram-negative
Streptococcus faecalis	*Haemophilusinfluenzae*
Streptococcus pneumoniae	*Escherichia coli*
Streptococcus pyogenes	*Proteus mirabilis*
Streptococcus viridans	*Salmonella species*
Staphylococcus aureus (penicillin sensitive)	*Shigella species*
Clostridium species	*Bordetella pertussis*
Corynebacterium species	*Brucella species*
Bacillus anthracis	*Neisseria gonorrhoeae*
Listeria monocytogenes	*Neisseria meningitidis*
	Vibrio cholera
	Pasteurellaseptica

5.2 Pharmacokinetic properties:

Amoxicillin is more completely and rapidly absorbed than Ampicillin and is reported to produce peak antibiotic plasma concentrations that are upto 2 ½ times as high as those from the same dose of Ampicillin. Peak plasma Amoxicillin concentrations of about 5Ug /ml have been observed 1 to 2 hours after a dose of 250mg, with detectable amounts present for upto 8 hours. The presence of food in the stomach does not appear to diminish absorption significantly. Upto 20% is bound to plasma proteins in the circulation and plasma half-lives of about 1 hour have been reported. The half-life may be longer in neonates and the elderly because of incomplete renal function. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. Amoxicillin diffuses across the placenta, little appears to be excreted in breast milk. Amoxicillin is metabolised to an extent to penicilloic acid, which is excreted in the urine. About 60% of an oral dose of Amoxicillin is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion.

5.3 Preclinical safety data:

There are no preclinical data of relevance to the prescriber which are additional to those already stated

6. Pharmaceutical Particulars:

6.1 List of excipients

Amoxiren Capsules contains the following excipients:

magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precaution for storage

Do not store above 30ºC. Protect from light. Keep out of reach of Children.

6.5 Nature and contents of container

10 Capsules are packed in Aluminium/PVC blister; such ten blisters are packed in a unit carton along with literature insert.
1000 Capsules packed in polythene bag and contained in HDPE Container with leaflet.

6.6 Special precautions for disposal

No special precaution.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:
Rene Industries Ltd
Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

Manufactured by:
Rene Industries Ltd
Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER:

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable