SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Name: Amoxicillin for Oral Suspension

Strength: 125mg, 250mg/5ml, 100ml

Pharmaceutical Form: powder for oral suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

API: Amoxicillin

Excipients: ASPARTAME, CARMINE, EDTA ETHYL ALCOHOL 80%, PROVIDONE SILICON DIOXIDE, SODIUM BENZOATE, SODIUM CARBOXYMETHYLCELLULOSE, SODIUM CITRATE, STRAWBERRY FLAVOUR, SUCROSE.

3. PHARMACEUTICAL FORM

Powder for Oral Suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Amoxicillin is indicated for the treatment of the following bacterial infections caused by amoxicillin-sensitive gram-positive and gram-negative pathogens:

- Infections or the upper respiratory tract, including infections of the ears,nose and throat: Acute otitis media,acute sinusitis and bacterial pharyngitis.
- Infections of the lower respiratory tract: Acute exacerbation of chronic bronchitis, community-acquired pneumonia.
- Infections of the lower urinary tract: Cystitis.
- Prophylaxis of endocarditis in patients at risk i.e. surgery in the oral cavity or upper airways.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Susceptibility of the causative organism to the treatment should be tested (if possible), although therapy may be initiated before the results are available.

4.2. Posology and method of administration

The preparation is administered orally with a measuring spoon. The measuring spoon is included in the package. The ready-for-use suspension should be taken with a glass o water.

The absorption of amoxicillin is not reduced by food intake.

Administration to babies: The prescribed dosage is administered undiluted to the baby; milk or tea should be given afterwards.

Treatment of Infection:

In general the therapy should be continued for 2 to 3 days following the disappearance of symptoms.In β-haemolytic streptococcal infections the duration of therapy should be 6-10 days in order to achieve eradication of the organism.

Adult dosage (including elderly patients) :

Standard dosage:

The usual dosage covers arrange from 750 mg to 3g amoxicillin daily in divided doses. In some areas 1500mg amoxicillin daily in divided doses are recommended as the upper usual dose.

Children's dosage (under 40 kg)

The daily dosage for children is 40-90mg/kg/day in two to three divided doses*(not exceeding 3g/day)depending on the indication.

Children weighing more than 40 kg should be given the usual adult dosage.

Acute otitis media: In areas with high prevalence of pneumococci with reduced susceptibility to penicillins, dosage regimens should be guided by national/local recommendations.
Dosage in impaired renal function:
The dose should be reduced in patients with severe renal function impairment. In patients with a renal clearance of less than 30 ml/min an increase in the dosage interval and a reduction in the total daily dose is recommended.

Creatinine clearance ml/min	Dose	Interval between administration
>30	No adjustment necessary	
10-30	500mg	12h
<10	500mg	24h

Renal impairment in children under 40kg:

Creatinine clearance ml/min	Dose	Interval between administration
>30	Usual dose	No adjustment necessary
10-30	Usual dose	12h(corresponding to 2/3 of the dose)
<10	Usual dose	24h(corresponding to 1/3 of the dose)

Dosage in impaired hepatic function
No dose reduction is necessary as long as the renal function isnot impaired.
Prophylaxis for endocarditis
For'the prevention of endocarditis,in patients not having general anaesthetic, 3g amoxicillin are given orally in the hour preceding the surgical procedure, followed by (6 hours later)a further 3g dose,if considered necessary.
For children: 50 mg amoxicillin/kg body weight given as a single dose one hour preceding the surgical procedure.
For further details and description of patients at risk local official guidelines for the prevention of endocarditis should be consulted.
4.3. Contraindications
Amoxicillin is contraindicated in patients with:

- Hypersensitivity to penicillin; a cross-allergy to other beta-lactams such as cephalosporins should be taken into account.
- Hypersensitivity to any of the excipients.

4.4. Special warnings and special precautions for use
WARING
Do not take this medicine and consult your doctor if the answer to any of the following is yes(for you/your child):
You have ever had a bad reaction or allergy to any penicillin-type antibiotic.
You have ever had a skin rash or swelling of the face or neck or shortness of breath when taking any antibiotic.
You have allergic to any of the ingredients contained in this medicine.

PRECAUTIONS

Check with your doctor or pharmacist before taking this medicine if:

You suffer from kidney problems, as you may require a lower dose than normal.

You have glandular fever, cytomegalovirus (CMV) infection or certain types of leukaemia - you may be at greater risk of developing a rash when you take this medicine.

Check With your doctor before you take this medicine if you are pregnant or breast-feeding.

4.5. Interaction with other FPPs and other forms of interaction

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin.

Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bactericidal effects of penicillin. This has been demonstrated in vitro; however, the clinical significance of this interaction is not well documented.

In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

4.6. Pregancy and lactation

Pregnancy:

Teratogenic Effects. Pregnancy Category B.Reproduction studies have been performed in mice and rats at doses up to 10 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted. This effect may also occur with amoxicillin.

Nursing Mothers:

Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

4.7. Effects on ability to drive and use machines

No records.

4.8. Undesirable effects

As with all medicines, some people may experience side effects with amoxicillin.

If you experience any of the following events STOP taking your medicine, tell your doctor or go to your nearest hospital immediately.

Hypersensitivity or severe allergic reaction including swollen face or breathing problems.

Allergic skin reactions with itching e.g. hives, nettle rash, blistering or peeling of the skin. If you start to itch or get a rash, STOP taking amoxicillin and tell your doctor immediately.

Convulsions may occur in patients on high doses or with kidney problems.

Notice your urine becoming darker or your faeces becoming paler.

Notice your skin or the white of your eyes turning yellow (jaundice).

Difficulty or discomfort in passing urine or having cloudy urine.

The following symptoms are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.

Common side effects (i.e. more than 1 in 100 people):
Nausea (feeling sick) or diarrhoea.
Uncommon side effects (i.e.between 1 in 100 and 1t in 1 ,000 people):
Vomiting.
Very rare side effects (i.e.less than 1 in 10,000 people):
Thrush (a yeast infection of the vagina,mouth or skin folds). You can get treatment for thrush from your doctor or pharmacist.
Tooth discolouration. The colour usually returns to normal with brushing.
Blackening of the tongue.
Inflammation of the kidney.
Excessive body movements (hyperkinesia) or dizziness.
Reduction (reversible) in blood cell counts including anaemia (a reduction in the body's red blood cells or haemoglobin which may be characterised by feeling weak or light-headed) or a linger time taken for blood to clot.
Crystalluria, forming or crystals in the urine.
If you notice any side effects not mentioned in this leaflet please inform your doctor or pharmacist.
4.9. Overdose
Symptoms of overdose:
Amoxicillin is not generally associated with acute toxic effects,even when accidentally consumed in high dose. Overdosage can lead to symptoms such as gastrointestinal renal and neuro-psuchic disturbances and electrolyte inbalance. In patients with severely impaired renal function, large overdoses can result in signs of renal toxicity; crystalluria is possible.
Management of overdose:
There is no specific antidote for an overdose of amoxicillin.
Treatment consists primarily of administration of activated charcoal (a gastric lavage is usually not necessary), or symptomatic measures. Particular attention should be paid to the water and electrolyte balance of the patients.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Bacteria may be resistant to amoxicillin due to production of beta-lactamases which hydrolyse aminopenicillins, due to ateration in penicilin-binding protein, due to impermeability to the drug, or due to drug efflux pumps. One or more of these mechanisms may co-exist in the same organism, leading to a variable and unpredictable cross-resistance to other beta-lactams and to antibacterial drugs of other classes.
5.2. Pharmacokinetic properties
The absolute bioavailability of amoxicillin depends on the dose and ranges between 75 and 90%, In the dose range betwen 250mg and 1000mg the bioavailability(parameters: AUS and Cmax) is linearly proportional to the dose. At higher doses the extent of absorption decreases. The absorption is not affected by concomitant food intake. Oral administration of a singe dose of 500mg amoxicillin results in plasma concentrations of 6-11mg/L. After administration of a single dose of 3g amoxicillin, the plasma concentrations reach 27 mg/L. Peak plasma concentrations are present about 1-2 hours after administration.
5.3. Preclinical safety data
H. Pylori Eradication to Reduce the Risk of Duodenal UlcerRecurrence: Randomized, double-blind

clinical studies performed in the United States in patients with H. pylori and duodenal ulcer disease (defined as an active ulcer or history of an ulcer within 1 year) evaluated the efficacy of lansoprazole in combination with amoxicillin capsules and clarithromycin tablets as triple 14 day therapy, or in combination with amoxicillin capsules as dual 14 day therapy, for the eradication of H. pylori. Based on the results of these studies, the safety and efficacy of 2 different eradication regimens were established:

Triple Therapy: Amoxicillin 1 gram twice daily/clarithromycin 500 mg twice daily/lansoprazole 30 mg twice daily.

Dual Therapy: Amoxicillin 1 gram three times daily/ lansoprazole 30 mg three times daily.

All treatments were for 14 days. H. pylori eradication was defined as 2 negative tests (culture and histology) at 4 to 6 weeks following the end of treatment.

Triple therapy was shown to be more effective than all possible dual therapy combinations. Dual therapy was shown to be more effective than both monotherapies. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence.

H. pylori Eradication Rates – Triple Therapy (amoxicillin/clarithromycin/lansoprazole) Percent of Patients Cured [95% Confidence Interval] (Number of Patients)

Study	Triple Therapy	Triple Therapy
	Evaluable Analysis†	**Intent-to-Treat Analysis‡**
Study 1	92§ [80 to 97.7] (n = 48)	86§ [73.3–93.5] (n = 55)
Study 2	86ll [75.7–93.6] (n = 66)	83ll [72 to 90.8] (n = 70)

† This analysis was based on evaluable patients with confirmed duodenal ulcer (active or within 1 year) and H. pylori infection at baseline defined as at least 2 of 3 positive endoscopic tests from CLOtest®, (Delta West Ltd., Bentley, Australia), histology, and/or culture. Patients were included in the analysis if they completed the study. Additionally, if patients dropped out of the study due to an adverse event related to the study drug, they were included in the analysis as failures of therapy.

‡ Patients were included in the analysis if they had documented H. pylori infection at baseline as defined above and had a confirmed duodenal ulcer (active or within 1 year). All dropouts were included as failures of therapy.

§ ($p < 0.05$) versus lansoprazole/amoxicillin and lansoprazole/clarithromycin dual therapy.

ll ($p < 0.05$) versus clarithromycin/amoxicillin dual therapy.

H. pylori Eradication Rates – Dual Therapy (amoxicillin/lansoprazole) Percent of Patients Cured [95% Confidence Interval] (Number of Patients)

Study	Dual Therapy	Dual Therapy
	Evaluable Analysis¶	**Intent-to-Treat Analysis††**
Study 1	77‡‡ [62.5–87.2] (n=51)	70‡‡ [56.8–81.2] (n=60)
Study 2	66§§ [51.9–77.5] (n=58)	61§§ [48.5–72.9] (n=67)

¶ This analysis was based on evaluable patients with confirmed duodenal ulcer (active or within 1 year) and H. pylori infection at baseline defined as at least 2 of 3 positive endoscopic tests from CLOtest®, histology, and/or culture. Patients were included in the analysis if they completed the study. Additionally, if patients dropped out of the study due to an adverse event related to the study drug, they were included in the analysis as failures of therapy.

†† Patients were included in the analysis if they had documented H. pylori infection at baseline as defined above and had a confirmed duodenal ulcer (active or within 1 year). All dropouts were included as failures of therapy.

‡‡ ($p < 0.05$) versus lansoprazole alone.

§§ ($p < 0.05$) versus lansoprazole alone or amoxicillin alone.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Excipients: ASPARTAME, CARMINE, EDTA ETHYL ALCOHOL 80%, PROVIDONE SILICON DIOXIDE, SODIUM BENZOATE, SODIUM CARBOXYMETHYLCELLULOSE, SODIUM CITRATE, STRAWBERRY FLAVOUR, SUCROSE.

6.2. Incompatibilities

N/A

6.3 Shelf Life

3 years

6.4 Special Precautions for storage

Do not store above 25℃.

Keep the container tightly closed.

6.5 Nature and contents of container

Plastic bottle.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

FUREN PHARMACEUTICAL GROUP CO., LTD.

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

05871/07781/REN/2021

9. DATE OF FIRST RENEWALOF THE AUTHORISATION

Apr 16, 2021

10. DATE OF REVISION OF THE TEXT

V2 on March 2018.