# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Zanitin Duo Injection 1.2g

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Ingredients | Qty in mg / Vial |
|---|---|
| Amoxicillin sodium | Amoxicillin sodium equivalent to amoxicillin 1000mg |
| Clavulanate potassium | Clavulanate potassium equivalent to clavulanic acid 200mg |
| Without excipients | |

## 3. PHARMACEUTICAL FORM

Powder for Injection

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Zanitin infection is indicated for the treatment of infections caused by amoxicillin resistant organisms producing β-lactamases sensitive to clavulanic acid: Upper respiratory tract infection such as sinusitis, otitis media, tonsillitis. Low respiratory tract infection such as bronchitis (caused by amoxicillin resistant β-lactamase producing Escherichia coli, Haemophilus influenzae and Haemophilus para-influenzae) pneumonia. Urinary tract infections such as cystitis, urethritis, pyelonephritis. Skin and soft tissues infection: Zanitin will also be effective in the treatment of infections caused by amoxicillin sensitive organisms at the appropriate amoxicillin dosage since in this situation the alavulanic acid component does not contribute to the therapeutic effect.

### 4.2 Posology and method of administration

| Product | Upper respiratory | Lower Respiratory | Urinary tract | Skin and soft |
|---|---|---|---|---|
| Adults | Tract infections | Tract infections | Infections | Tissue infections |
| Moxyclav 1.2 | 1 vial | 1 vial | 1 vial | 1 vial |
| | 1) 6-8 hourly | 1) 6-8 hourly | 1) 6-8 hourly | 1) 6-8 hourly |

Amoxicillin resistant organisms

| Product | Upper respiratory | Lower Respiratory | Urinary tract | Skin and soft |
|---|---|---|---|---|
| Adults | Tract infections (Otitis Media) H. influenzae H. parainfluenzae | Tract infections (Bronchitis) H. influenzae H. parainfluenzae | E. coli Klebsiella pneumoniae | Tissue infections Staphylococcus aureus |
| Moxyclav 1.2 | 1 vial | 1 vial | 1 vial | 1 vial |
| | 1) 6-8 hourly | 1) 6-8 hourly | 1) 6-8 hourly | 1) 6-8 hourly |

1) Intravenous therapy should not be continued for longer than 10 days, 2) Without review and the total daily administration of clavulanic acid should not exceed 800mg.

Note: 1) Insufficient evidence exists at present to recommend an intravenous dosage in children. 2) Patients with renal impairment: each Moxyclav 1.2 vial contains 1.0 mmol of potassium and 2.8 mmol of sodium (approx) as both the amoxicillin and clavulanic acid component of Moxyclav is excreted by the kidneys, accumulation of both may occur in patients with renal insufficiency. In these cases monitoring of the serum levels and a reduction in the number of administrations of the suggested dosage may be required. Experiences in a limited number of patients with varying degrees in renal insufficiency suggests that the following schedule of dosage based on the creatinine clearance of the patient, may be used as a guideline:

| Creatinine clearance | Dosage |
|---|---|
| ＞70 mL/min | No dosage adjustment |
| 10-30 mL/min | 1.2g Moxyclav stat and 600 mg 12 hourly |
| <10 mL/min | 1.2g Moxyclav stat and 600 mg daily |

Directions for use: Moxyclav injection can be reconstituted by dissolving in 20 ml water for injection BP. For intravenous infusion, the reconstituted vial should be further diluted with the desired volume of a suitable infusion fluid. When reconstituted it must be used within 20 minutes.

## 4.3 Contraindications

Allergy to penicillins and cephalosporins. Safety in pregnancy has not been established. Zanitin is contra-indicated in patients with a previous history of Zanitin associated jaundice/hepatic dysfunction. Safety and efficacy in children has not been established with the parenteral form of Zanitin.

## 4.4 Special warnings and precautions for use

If an allergic reaction occurs Moxyclav should be discontinued. Moxyclav should not be given intramuscularly or subcutaneously. Moxyclav formulations, as with other penicillins and cephalosporins,

should not be mixed with aminoglycosides in the same syringe or giving set, as substantial inactivation of the aminoglycosides can result

Precautions: Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy. Since Moxyclav contains amoxicillin, 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 is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxicillin is used. Moxyclav should be given with caution to patients with lymphatic leukemia since they are especially susceptible to amoxicillin induced skin rashes. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Aerobacter, pseudomonas or candida), the agent should be discontinued and/or appropriate therapy instituted.

## 4.5 Interaction with other medicinal products and other forms of interaction

Probenecid decreases the renal tubular secretion of amoxicillin, but does not affect clavulanic acid excretion. Concurrent use with Moxyclav may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid. The concurrent administration of allopurinol and ampicillin substantially increases the incidence of rashes in patients receiving both agents as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients. There is no data on Moxyclav and allopurinol administered concurrently. No information is available about the concurrent use of Moxyclav and alcohol. However, the ingestion of alcohol whilst being treated with some other β-lactam antibiotics has precipitated a disulfiram (antibuse) like reaction in some patients. Therefore, the ingestion of alcohol should be avoided during and for several days after treatment with Moxyclav. Following administration of ampicillin to pregnant women a transient decrease in plasma concentration of total conjugate oestriol, oestriol-glucuronide, conjugated oestrone and oestradiol has been noted. This effect may also occur with amoxicillin and therefore Moxyclav. Moxyclav may reduce the efficacy of oral contraceptives and patients should be warned accordingly. The use of this antibiotic 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. Intravenous administration can cause local irritation, induration and phlebitis at the injection site.

## 4.6 Pregnancy and lactation

Pregnancy& Lactation:

Amoxycillin is excreted in the milk; there is no data on the excretion of clavulanic acid in human milk. Therefore, caution should be exercised when Moxyclav is administered to a nursing woman.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

The most frequently reported adverse effects are diarrhea, nausea, vomiting, abdominal pain, skin rashes, urticarial, and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes. The incidence and severity of adverse effects, particularly nausea and diarrhea, increased with the higher recommended dose and can be minimized by administering the agent at the start of a meal.

## 4.9 Overdose

Overdosage with amoxicillin is usually asymptomatic. However, gastrointestinal effects such as nausea, vomiting and diarrhea may be evident and symptoms of water and electrolyte imbalance should be treated symptomatically. Adequate fluid intake and urinary output must be maintained to minimize the possibility of crystalluria. Amoxicillin may be removed from the circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with information from a single patient with renal insufficiency all suggest that this compound may also be removed by haemodialysis.

# 5. PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacological category: Semisynthetic extended spectrum penicillin with betalctamase inhibitor combination.

Pharmacological action: Bactericidal action: The amoxicillin component of the Moxyclav exert a bactericidal action against many strains of Gram-positive and Gram-negative organisms. The clavulanic acid component has very little bactericidal action. It does however, by inactivation of susceptible β-lactamases, protect amoxicillin from degradation by a large number of β-lactamase enzymes produced by penicillin resistant strains of organisms.

## 5.2 Pharmacokinetic properties

Absorption: Amoxicillin is stable in the presence of acidic gastric secretions. Peak blood levels are achieved 1-2 hours after administration. There is a linear dose response in peak serum levels. The pharmacokinetics of amoxicillin and clavulanic acid are closely allied and neither is adversely affected by the presence of food in the stomach.

Distribution: Approximately 18% of the total 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 penicillin and this may apply to amoxicillin.

Excretion: The elimination half-life of approximately 1 hour. Co-administration of probenecid has little effect on the excretion of the clavulanic acid component of the formulation. Small amounts of amoxicillin are also excreted in the faeces and bile.

## 5.3 Preclinical safety data

Not Applicable

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

None

### 6.2 Incompatibilities

None stated.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Do not store above 25 ℃. Protect from sunlight. Keep away from the reach of children.

### 6.5 Nature and contents of container

20 ml molded glass vial, 5 such vials in a box with a leaflet.

### 6.6 Special precautions for disposal and other handling

None

## 7. MARKETING AUTHORISATION HOLDER

Shalina Healthcare DMCC,

30th Floor, Almas Tower, Jumeirah Lakes Towers, Dubai, UAE.

## 8. MARKETING AUTHORISATION IN OTHER COUNTRIES

None