

## **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

### **1. Name of the Medicinal Product**

Omnicear® 625 mg Tablets

(Amoxicillin 500 mg + Clavulanic acid 125 mg)

### **2. Qualitative and Quantitative Composition**

Each film-coated tablet contains:

- Amoxicillin trihydrate equivalent to 500 mg Amoxicillin
- Potassium clavulanate equivalent to 125 mg Clavulanic acid

Excipients: Microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, povidone, magnesium stearate, hypromellose, titanium dioxide, talc, polyethylene glycol.

### **3. Pharmaceutical Form**

Film-coated tablet.

White to off-white, oval, biconvex tablet, debossed "OMC 625" on one side.

### **4. Clinical Particulars**

#### **4.1 Therapeutic Indications**

Treatment of infections due to beta-lactamase producing organisms, including:

- Sinusitis, otitis media, tonsillitis, pharyngitis
- Acute exacerbations of chronic bronchitis, pneumonia
- Urinary tract infections (cystitis, pyelonephritis)
- Skin/soft tissue infections (cellulitis, abscesses, bites)
- Bone/joint infections (osteomyelitis)
- Dental infections (abscesses)

#### **4.2 Posology and Method of Administration**

- Adults & children  $\geq 40$  kg: 1 tablet every 12 hours. For severe infections, 1 tablet every 8 hours.
- Children  $< 40$  kg: use paediatric suspensions.
- Renal impairment: dose adjustment required if CrCl  $< 30$  mL/min.
- Hepatic impairment: use with caution, monitor LFTs.
- Administration: oral, at the start of a meal.

### **4.3 Contraindications**

- Hypersensitivity to penicillins or beta-lactams
- Previous cholestatic jaundice/hepatitis with co-amoxiclav
- Severe renal impairment (formulation dependent)

### **4.4 Warnings & Precautions**

- Severe hypersensitivity reactions possible.
- Monitor LFTs in hepatic impairment.
- Risk of antibiotic-associated colitis.
- Crystalluria risk → maintain hydration.

### **4.5 Interactions**

- Warfarin (increased INR)
- Allopurinol (rash risk)
- Probenecid (reduces renal clearance)
- Methotrexate (increased toxicity)
- Mycophenolate (reduced metabolite levels)

### **4.6 Pregnancy/Lactation**

- Use if benefits outweigh risks.
- Passes into breast milk (possible diarrhoea/thrush in infants).

### **4.7 Effects on Ability to Driving/Use Machines**

May cause dizziness, convulsions, or allergic reactions.

### **4.8 Undesirable Effects**

- Very common: Diarrhoea
- Common: Nausea, vomiting, rash, thrush
- Uncommon: Headache, dizziness, indigestion
- Rare: Hepatitis, jaundice, severe skin reactions
- Very rare: Hematologic effects, interstitial nephritis

## **4.9 Overdose**

- GI upset, crystalluria, renal impairment possible.
- Symptomatic treatment, hydration, hemodialysis removes drug.

## **5. Pharmacological Properties**

### **5.1 Pharmacodynamics**

Broad-spectrum penicillin + beta-lactamase inhibitor. ATC Code J01CR02.

### **5.2 Pharmacokinetics**

- Absorbed rapidly, enhanced by food.
- Half-life ~1 hr.
- Excreted via urine.

### **5.3 Preclinical Safety**

No evidence of mutagenicity or carcinogenicity.

## **6. Pharmaceutical Particulars**

### **6.1 List of Excipients**

Microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, povidone, magnesium stearate, hypromellose, titanium dioxide, talc, polyethylene glycol.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

24 months

### **6.4 Special Precautions for Storage**

Store below 25°C. Protect from moisture. Keep out of reach of children.

### **6.5 Nature and Contents of Container**

PVC/aluminium foil blister packs of 6, 10, 14, or 20 film-coated tablets.

### **6.6 Special Precautions for Disposal**

No special requirements. Dispose in accordance with local regulations.

**7. Marketing Authorisation Holder / Manufacturer**

A.C. Drugs Limited  
Plot C5/C6 Old Airport Road  
Emene, Enugu, Nigeria

**8. Marketing Authorisation Number(s)**

**9. Date of First Authorisation / Renewal of the Authorisation**

**10. Date of Revision of the Text**

September 2025

**11. Legal Category**

Prescription Only Medicine (Rx)