Auximo Powder For Oral Suspension

1. Name of the medicinal product

Auximo 200mg/28.5mg Powder For Oral Suspension
Auximo 400mg/57mg Powder For Oral Suspension

2. Composition

Active ingredient:

Auximo 200mg/28.5mg Powder for Oral Suspension: When reconstituted, each 5 mL contains 200mg amoxicillin (as amoxicillin trihydrate) and 28.5mg clavulanic acid [as potassium clavulanate – Syloid (1:1)].

Auximo 400mg/57mg Powder for Oral Suspension: When reconstituted, each 5 mL contains 400mg amoxicillin (as amoxicillin trihydrate) and 57mg clavulanic acid [as potassium clavulanate – Syloid (1:1)].

Excipients:

Citric acid, sodium citrate, strawberry flavor, silica colloidal anhydrous, aspartame, mannitol and hypromellose.

3. Pharmaceutical form

Powder for oral suspension.
Dry, off-white powder with characteristic flavor which on reconstitution becomes an off-white suspension with a characteristic strawberry odour.

4. Indications

Auximo should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data.
Auximo for twice daily oral dosing, is indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactam producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered.

- *Upper respiratory tract infections (including ENT)* e.g. recurrent tonsillitis, sinusitis, otitis media.
- *Lower respiratory tract infections* e.g. acute exacerbations of chronic bronchitis, lobar and bronchopneumonia.
- *Urinary tract infections* e.g. cystitis, urethritis, pyelonephritis.
- *Skin and soft tissue infections* e.g. cellulitis, animal bites.
- *Dental infections* e.g. severe dental abscess with spreading cellulitis.

Susceptibility to Auximo will vary with geography and time (see *Pharmacological Properties, Pharmacodynamics* for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Mixed infections caused by amoxicillin-susceptible organisms in conjunction with Auximo susceptible beta-lactam-producing organisms may be treated with Auximo 200mg/28.5mg and Auximo 400mg/57mg Powder for Oral Suspension. These infections should not require the additional of another antibiotic resistant to beta-lactamases.

5. Dosage and administration

Dosage

- Dosage depends on the age, weight and renal function of the patient and the severity of the infection.
- Dosages are expressed throughout in terms of amoxicillin/clavulanate content except when doses are stated in terms of an individual component.
- To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of Auximo is optimized when taken at the start of a meal.
- Treatment should not exceed 14 days without review.
- Therapy can be started parenterally and continued with oral preparation.
- See *Method of administration* for preparation of the suspensions.
- The usual recommended daily dosage is:

- 25/3.6mg/kg/day in two divided doses for mild to moderate infections (upper respiratory tract infections e.g. recurrent tonsillitis, lower respiratory infections and skin and soft tissue infections).
- 45/6.4mg/kg/day in two divided doses for the treatment of more serious infections (upper respiratory tract infections e.g. otitis media and sinusitis, lower respiratory tract infections e.g. bronchopneumonia and urinary tract infections).

- No clinical data are available on doses above 45/6.4 mg/kg/day in children under 2 years.
- There is no clinical data for Auximo suspension 228 mg/ 5 mL and 457 mg/ 5 mL to make dosage recommendations for children under 2 months old.
- The tables below give dosage guidance for children.

Children over 2 years

25/3.6 mg/kg/day	2 – 6 years (13 – 21 kg)	5.0 mL (1 sachet) of Auximo 200mg/28.5mg twice daily.
	7 – 12 years (22 – 40 kg)	10.0 mL (2 sachets) of Auximo 200mg/28.5mg ***or*** 5.0 mL (1 sachet) of Auximo 400mg/57 mg twice daily.
45/6.4 mg/kg/day	2 – 6 years (13 – 21 kg)	10.0 mL (2 sachets) of Auximo 200mg/28.5mg ***or*** 5.0 mL (1 sachet) of Auximo 400mg/57mg twice daily.
	7 – 12 years	10.0 mL (2 sachets) of Auximo 400mg/57mg twice daily.

Children aged 2 months to under 2 years

Auximo 400mg/57mg Powder For Oral Suspension		
Body weight (kg)	**Lower dose at 25/3.6 mg/kg/day (mL every 12 hours)**	**Higher dose at 45/6.4 mg/kg/day (mL every 12 hours)**
2	0.3	0.6
3	0.5	0.8
4	0.6	1.1
5	0.8	1.4
6	0.9	1.7
7	1.1	2.0
8	1.3	2.3
9	1.4	2.5
10	1.6	2.8
11	1.7	3.1
12	1.9	3.4
13	2.0	3.7
14	2.2	3.9
15	2.3	4.2

Renal impairment

No adjustment in dose is required in patients with creatinine clearance greater than 30 mL/min.

Auximo 200mg/28.5mg and 400mg/57mg not recommended in patients with a creatinine clearance of less than 30 mL/min.

Hepatic impairment

Dose with caution; monitor hepatic function at regular intervals. There are insufficient data on which to base a dosage recommendation.

Method of administration

Auximo is for oral use.

Empty the contents of a sachet into a glass and add 5 mL of water and stir well until the powder is completely dispersed. Administer the full dose immediately after reconstitution. Rinse the glass with a small amount of water and administer the rinse immediately.

The reconstituted preparation is for immediate use only and any remaining reconstituted suspension should be discarded.

6. Contraindications

AUXIMO is contraindicated

- in patients with a history of hypersensitivity to beta-lactam, e.g. penicillins and cephalosporins.
- In patients with a previous history of AUXIMO-associated jaundice/hepatic dysfunction.

7. Special warnings and precautions for use

- Before initiating therapy with Auximo, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents.
- Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to Auximo. Drug-induced enterocolitis syndrome (DIES) has been reported mainly in children receiving amoxicillin/clavulanic acid. DIES is an allergic reaction with the leading symptom of protracted vomiting (1-4 hours after drug administration) in the absence of allergic skin or respiratory symptoms. Further symptoms could comprise abdominal pain, diarrhoea, hypotension or leucocytosis with neutrophilia. There have been severe cases including progression to shock.
  If an allergic reaction occurs, Auximo therapy must be discontinued immediately, and appropriate alternative therapy instituted.
- Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous (i.v) steroids and airway management (including intubation) may also be required.
- Auximo should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.
- Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.
- *Pseudomembranous colitis* has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.
- Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving Auximo and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.
- Changes in liver function tests have been observed in some patients receiving Auximo. The clinical significance of these changes is uncertain, but Auximo should be used with caution in patients with evidence of hepatic dysfunction.
- Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment has ceased.
- In patients with renal impairment Auximo 200mg/28.5mg and 400mg/57mg are not recommended.
- In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to

maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria.
- This medicine contains mannitol which may have a mild laxative effect.
- This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is considered essentially sodium-free.
- **WARNING:**
  Unsuitable for phenylketonurics.

8. Drug interactions

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use with AUXIMO may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There is no data on the concomitant use of AUXIMO and allopurinol.

In common with other antibiotics, AUXIMO may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

In the literature, there are rare cases of increased international normalized ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalized ratio should be carefully monitored with the addition or withdrawal of AUXIMO.

In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure.

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

9. Pregnancy and lactation

Pregnancy

Reproduction studies in animals (mice and rats at doses up to 10 times the human dose) with orally and parenterally administered amoxicillin and clavulanic acid have shown no teratogenic effects. In a single study in women with pre-term, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment with amoxicillin and clavulanic acid may be associated with an increased risk of necrotizing enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, unless considered essential by the physician.

Lactation

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

10. Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

11. Adverse reactions

The following terminologies have been used in order to classify the occurrence of undesirable effects. [Very common (≥1/10) Common (≥1/100 to <1/10) Uncommon (≥1/1000 to <1/100) Rare (≥1/10,000 to <1/1,000) Very rare (<1/10,000), not known (cannot be estimated from the available data)]

Infections and infestation

Common	Mucocutaneous candidosis

Blood and lymphatic system disorders

Rare	Reversible leucopenia (including neutropenia)
Rare	Thrombocytopenia
Very rare	Reversible agranulocytosis and haemolytic anaemia. Prolongation of bleeding time and prothrombin time

Immune system disorders

Very rare	Angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis

Nervous system disorders

Uncommon	Dizziness, headache
Very rare	Reversible hyperactivity, aseptic meningitis, convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Cardiac disorders

Very rare	Kounis syndrome

Gastrointestinal disorders

Adults

Very common	Diarrhoea
Common	Nausea, vomiting

Children

Common	Diarrhoea, nausea, vomiting

All populations

Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking Auximo at the start of a meal.

Uncommon	Indigestion
Very rare	Antibiotic-associated colitis (including *pseudomembranous colitis* and *haemorrhagic colitis, drug-induced enterocolitis syndrome*)
	Black hairy tongue
	Superficial tooth discolouration has been reported very rarely in children. Good oral hygiene may help to prevent tooth discolouration as it can usually be removed by brushing.

Hepatobiliary disorders

Uncommon	A moderate rise in AST and/or ALT has been noted in patients treated with beta-lactam class antibiotics, but the significance of these findings is unknown.
Very rare	Hepatitis and cholestatic jaundice. These events have been noted with other penicillin and cephalosporins.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. These events have been very rarely reported in children.

Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may be severe and in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Skin and subcutaneous tissue disorders	
Uncommon	Skin rash, pruritus, urticaria
Rare	Erythema multiforme
Very rare	Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalized exanthemous pustulosis (AGEP), and drug reaction with eosinophilia and systemic symptoms (DRESS) If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.
Not known	Linear IgA disease. Symmetrical drug-related intertriginous and flexural exanthema (SDRIFE).
Renal and urinary disorders	
Very rare	Interstitial nephritis, crystalluria

12. Overdosage

Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Gastrointestinal symptoms may be treated symptomatically with attention to the water electrolyte balance.

Amoxicillin crystalluria, in some cases leading to renal failure, has been observed (see *Special warnings and precautions for use*).

AUXIMO can be removed from the circulation by haemodialysis.

13. Pharmacological properties

Pharmacotherapeutic group: Combinations of penicillins, incl. beta-lactamase inhibitors

ATC code: J01CR02

Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The clavulanate in AUXIMO suspension anticipates this defence mechanism by blocking the beta-lactamase enzymes, thus rendering the organisms sensitive 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 AUXIMO it produces an antibiotic agent of broad-spectrum with wide application in hospital and general practice.

Pharmacodynamic effects

In the list below, organisms are categorised according to their *in vitro* susceptibility to AUXIMO.

***In vitro* susceptibility of microorganisms to Auximo**
Where clinical efficacy of Auximo has been demonstrated in clinical trials this is indicated with an asterisk (*). Organisms that do not produce beta-lactamase are identified (with $). If an isolate is susceptible to amoxicillin, it can be considered susceptible to Auximo.
Commonly susceptible species
Gram-positive aerobes: *Bacillus anthracis* *Enterococcus faecalis* *Listeria monocytogenes* *Nocardia asteroides* *Streptococcus pyogenes**$ *Streptococcus agalactiae**$ *Streptococcus* spp. (other beta-hemolytic)*$ *Staphylococcus aureus* (methicillin susceptible)* *Staphylococcus saprophyticus* (methicillin susceptible)

Coagulase negative staphylococcus (methicillin susceptible)
Gram-negative aerobes: *Bordetella pertussis* *Haemophilus influenzae** *Haemophilus parainfluenzae* *Helicobacter pylori* *Moraxella catarrhalis** *Neisseria gonorrhoeae* *Pasteurella multocida* *Vibrio cholerae*
Other: *Borrelia burgdorferi* *Leptospira ictterohaemorrhagiae* *Treponema pallidum*
Gram-positive anaerobes: *Clostridium* spp. *Peptococcus niger* *Peptostreptococcus magnus* *Peptostreptococcus micros* Peptostreptococcus spp.
Gram-negative anaerobes: *Bacteroides fragilis* *Bacteroides* spp. *Capnocytophaga* spp. *Eikenella corrodens* *Fusobacterium nucleatum* *Fusobacterium* spp. *Porphyromonas* spp. *Prevotella* spp.
Species for which acquired resistance may be a problem
Gram-negative aerobes: *Escherichia coli** *Klebsiella oxytoca* *Klebsiella pneumoniae** *Klebsiella* spp. *Proteus mirabilis* *Proteus vulgaris* *Proteus* spp. *Salmonella* spp. *Shigella* spp.
Gram-positive aerobes: *Corynebacterium* spp. *Enterococcus faecium* *Streptococcus pneumoniae*$* Viridans group streptococcus
Inherently resistant organisms
Gram-negative aerobes: *Acinetobacter* spp. *Citrobacter freundii* *Enterobacter* spp. *Hafnia alvei* *Legionella pneumophila* *Morganella morganii* *Providencia* spp. *Pseudomonas* spp.

Serratia spp. *Stenotrophomonas maltophilia* *Yersinia enterolitica*
Others: *Chlamydia pneumoniae* *Chlamydia psittaci* *Chlamydia* spp. *Coxiella burnetii* *Mycoplasma* spp.

Infections caused by amoxicillin-susceptible organisms are amenable to Auximo treatment due to its amoxicillin content. Mixed infections caused by amoxicillin susceptible organisms in conjunction with Auximo-susceptible beta-lactamase producing organisms may therefore be treated with Auximo.

14. Pharmacokinetics properties

Absorption

The two components of AUXIMO suspension 228.5mg/5ml and 457mg/5ml, amoxicillin and clavulanate, are each fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of AUXIMO is optimized when taken at the start of a meal.

The mean AUC values for amoxicillin are essentially the same following twice a day dosing with the Amoxicillin/clavulanic acid 875/125 mg tablet or three times a day dosing with the Amoxicillin/clavulanic acid 500/125 mg tablet, in adults. No differences between the 875 mg twice daily and 500 mg three times daily dosing regimes are seen when comparing the amoxicillin $T_{½}$, or C_{max} after normalization for the different doses of amoxicillin administered. Similarly, no differences are seen for the clavulanate $T_{½}$, C_{max} or AUC values after appropriate dose normalization.

The time of dosing of amoxicillin/clavulanic acid relative to the start of a meal has no marked effects on the pharmacokinetics of amoxicillin in adults. In a study of the amoxicillin/clavulanic acid 875/125 mg tablet, the time of dosing relative to ingestion of a meal had a marked effect on the pharmacokinetics of clavulanate. For clavulanate AUC and C_{max}, the highest mean values and smallest inter-subject variabilities were achieved by administration of amoxicillin/clavulanic acid at the start of a meal, compared to the fasting state or 30 or 150 minutes after the start of a meal.

The mean C_{max}, T_{max}, $T_{½}$ and AUC values for amoxicillin and clavulanate are given below for an 875 mg/125 mg dose of amoxicillin/clavulanic acid administered at the start of a meal.

Mean Pharmacokinetic Parameters

Drug administration	Dose (mg)	C_{max} (mg/L)	T_{max}* (hours)	AUC (mg.h/L)	$T_{½}$ (hours)
Amoxicillin / clavulanic acid 1g					
Amoxicillin	875	12.4	1.5	29.9	1.36
Clavulanate	125	3.3	1.3	6.88	0.92

*Median values

Amoxicillin serum concentrations achieved with Amoxicillin and clavulanic acid are similar to those produced by the oral administration of equivalent doses of amoxicillin alone.

Distribution

The pharmacokinetics of the two components of Amoxicillin and clavulanic acid are closely matched. Both clavulanate and amoxicillin have low levels of serum binding; about 70% remain free in the serum.

Doubling the dosage of Amoxicillin and clavulanic acid approximately doubles the serum levels achieved.

Non-clinical information

No further information of relevance.

15. Instruction for use

(a) Empty the contents of a sachet into a glass and add 5 mL of water.
(b) Stir well until the powder is completely dispersed.
(c) Administer the full dose immediately after reconstitution.
(d) Rinse the glass with a small amount of water and administer the rinse immediately.

The reconstituted preparation is for immediate use only and any remaining reconstituted suspension should be discarded.

16. Packaging

Auximo 200mg/28.5mg: Box of 1 aluminium pouch x 12 sachets x 0.8g.
Auximo 400mg/57mg: Box of 1 aluminium pouch x 12 sachets x 1.6g.

17. Storage condition

Do not store above 30°C, protect from light and moisture before and after opening the aluminium pouch.

18. Shelf life

24 months from the date of manufacture
After opening the aluminium pouch, the product should be used within 15 days.

19. Date of revision

03 June 2026

20. Name and address of manufacturer

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