SCHEDULING STATUS: **S4**

PROPRIETARY NAMES AND DOSAGE FORM:

SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ powder for injection

SANDOZ CO-AMOXYCLAV 0,6 g 20 mℓ powder for injection

SANDOZ CO-AMOXYCLAV 1,2 g 20 mℓ powder for injection

SANDOZ CO-AMOXYCLAV 1,2 g 50 mℓ powder for injection

COMPOSITION:

Each Sandoz Co-amoxyclav 0,6 g 10 mℓ vial and Sandoz Co-amoxyclav 0,6 g 20 mℓ vial contains amoxycillin sodium equivalent to 500 mg of amoxycillin and potassium clavulanate equivalent to 100 mg clavulanic acid.

Each Sandoz Co-amoxyclav 1,2 g 20 mℓ vial and Sandoz Co-amoxyclav 1,2 g 50 mℓ vial contains amoxycillin sodium equivalent to 1000 mg of amoxycillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

A 20.1.2 Penicillins

PHARMACOLOGICAL ACTION:

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g is a combination of amoxycillin and clavulanic acid. Amoxycillin is a semisynthetic beta-lactamase susceptible penicillin, which has *in vitro* bactericidal activity against a broad spectrum of non beta-lactamase-producing Gram positive and Gram negative organisms. The spectrum of activity does not include those organisms that produce beta-lactamases, namely resistant *staphylococci*, and all strains of *Pseudomonas, Klebsiella* and *Enterobacter*.

Clavulanic acid has been shown *in vitro* to be an irreversible inhibitor of beta-lactamases produced by: S*taphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Haemophilus influenzae, Neisseria gonorrhoea* and *Bacteroides fragilis.* Clavulanic acid does not inactivate the chromosomally mediated (Sykes type 1 cephalosporinase) beta-lactamases produced by *Acinetobacter* species, *Citrobacter* species, *Enterobacter, Indole* positive *Proteus, Providencia* species and *Serratia marcescens. In vitro* the formulation showed synergism against amoxycillin-resistant organisms, with no evidence of antagonism and the activity was not reduced in the presence of serum (*in vitro* activity does not necessarily imply *in vivo* efficacy). The clavulanic acid component has very little bactericidal action.

Pharmacokinetic properties:

Absorption:

Amoxycillin is stable in the presence of acidic gastric secretions. Peak blood levels are achieved 1 to 2 hours after administration. There is a linear dose response in peak serum levels. The pharmacokinetics of amoxycillin 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 plasma amoxycillin content is protein bound. Amoxycillin diffuses readily into most body tissues with the exception of the brain and spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins and this may apply to amoxycillin.

Excretion:

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

INDICATIONS:

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g formulations are indicated for the treatment of infections caused by amoxycillin resistant organisms producing beta-lactamases sensitive to clavulanic acid:

- Upper respiratory tract infections such as sinusitis, recurrent otitis media and tonsillitis.
- Lower respiratory tract infections such as bronchitis and bronchopneumonia.
- Genito-urinary tract infections such as cystitis, urethritis and pyelonephritis.
- Skin and soft tissue infections.

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g formulations will also be effective in the treatment of infections caused by amoxycillin sensitive organisms at appropriate amoxycillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

In the treatment of infections caused by *Pseudomonas aeruginosa*, an aminoglycoside should be administered concomitantly.

CONTRAINDICATIONS:

Hypersensitivity to penicillins or to cephalosporins. Cross-sensitivity between penicillins and cephalosporins is well documented. SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g is contraindicated in patients with a previous history of amoxycillin/clavulanic acid-associated jaundice or hepatic dysfunction.

Safety and efficacy in children has not been established with the parenteral forms of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g.

WARNINGS AND SPECIAL PRECAUTIONS:

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Before initiating therapy with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens.

Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/ or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity, who have experienced severe reactions when treated with cephalosporins.

If an allergic reaction occurs SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should be discontinued and the appropriate therapy instituted. Serious anaphylactic reactions may require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation may also be required

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should be avoided if infectious mononucleosis is suspected, since the occurrence of a mobiliform rash has been associated with this condition following use of amoxycillin.

Prolonged use may result in overgrowth of non-susceptible organisms. Pseudomembranous enterocolitis has been reported.

Prolongation of prothrombin time has been reported rarely in patients receiving SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently.

Periodic assessment of organ function including renal, hepatic and haematopoietic functions, are advisable during prolonged therapy.

Transient hepatitis and cholestatic jaundice has been reported. SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should be used with caution in patients with evidence of hepatic dysfunction. SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should not be used in patients with a glomerular filtration rate of less than 30 mℓ/min.

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should not be given intramuscularly or subcutaneously. SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g IV formulations, should not be mixed with aminoglycosides in the same syringe or giving set, as substantial inactivation of the aminoglycosides can result.

Caution is needed when administering amoxycillin to patients with syphilis, as the Jarisch-Herxheimer reaction may occur in these patients.

When high doses are administered, adequate fluid intake and urinary output must be maintained.

The sodium content must be taken into account in patients on a sodium-restricted diet if the administration of high doses is necessary.

The use of lignocaine or benzyl alcohol together with amoxycillin must be used only when administering an intramuscular injection and not given intravenously.

Since SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g contains amoxycillin, 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 amoxycillin is used. SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxycillin-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.

Impaired hepatic function:

Changes in liver function tests have been observed in some patients receiving SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g. It should be used with care in patients with evidence of severe hepatic dysfunction.

Impaired renal function:

In patients with moderate or severe renal impairment SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g dosage should be adjusted (see “DOSAGE AND DIRECTIONS FOR USE”).

Use in lactation:

Amoxycillin is excreted in breast milk; there is no data on the excretion of clavulanic acid in human milk. Therefore caution should be exercised when SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g is administered to a nursing woman.

The use of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g 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.

INTERACTIONS:

Probenecid decreases the renal tubular secretion of amoxycillin, but does not affect clavulanic acid excretion. Concurrent use with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g may result in increased and prolonged blood levels of amoxycillin but not of clavulanic acid.

SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

The concomitant 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.

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxycillin.

Interaction with laboratory test:

It is recommended that when testing for the presence of glucose in urine during SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of amoxycillin, false positive readings are common with chemical methods.

PREGNANCY AND LACTATION:

Use in pregnancy:

The safety of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g in pregnancy has not been established.

Use in lactation:

Amoxycillin is distributed into breast milk. Although significant problems in humans have not been documented, the use of amoxycillin by nursing mothers may lead to sensitisation, diarrhoea, candidiasis and skin rash in the infant.

DOSAGE AND DIRECTIONS FOR USE:

Directions for use:

SANDOZ CO-AMOXYCLAV 0,6 g powder for injection can be reconstituted by dissolving in 10 mℓ or 20 mℓ sterile water for injection.

SANDOZ CO-AMOXYCLAV 1,2 g powder for injection can be reconstituted by dissolving in 20 mℓ or 50 mℓ sterile water for injection.

When a diluent is added a transient pink colour will be observed where after the solution will rapidly become clear again. For intravenous infusion, the reconstituted vial should be further diluted with the desired volume of a suitable infusion fluid. "See below"

Compatibility and stability:

The period of stability of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g infusion fluids after reconstitution and dilution are as follows:

			Stability results (hours)	
			5 °C	**25 °C**
SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ and 20 mℓ	0,9 % Sodium chloride	100 mℓ	< 10 hours	5 hours
SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ and 20 mℓ	Sodium lactate (1/6 M)	100 mℓ	< 8 hours	< 3 hours
SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ and 20 mℓ	Ringers solution	100 mℓ	10 hours	5 hours
SANDOZ CO-AMOXYCLAV 0,6g	Hartmann's solution/Ringers Lactate	100 mℓ	< 8 hours	< 2 hours

10 mℓ and 20 mℓ				
SANDOZ CO-AMOXYCLAV 1,2 g *20 mℓ and 50 mℓ*	0,9 % Sodium chloride	100 mℓ	< 10 hours	5 hours
SANDOZ CO-AMOXYCLAV 1,2 g *20 mℓ and 50 mℓ*	Sodium lactate (1/6M)	100 mℓ	< 8 hours	< 3 hours
SANDOZ CO-AMOXYCLAV 1,2 g *20 mℓ and 50 mℓ*	Ringers solution	100 mℓ	10 hours	5 hours
SANDOZ CO-AMOXYCLAV 1,2 g *20 mℓ and 50 mℓ*	Hartmann's solution/Ringers Lactate	100 mℓ	< 8 hours	< 2 hours

* For storage at 5 °C, the reconstituted solutions should be added to a pre-refrigerated bag of infusion fluid. For use, the solution should be allowed to reach room temperature and then administered without delay.

Administration:

Note: **SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g IV vials are not suitable for intramuscular or subcutaneous administration.**

The reconstituted vials can be administered intravenously by injection (2 minutes) or slow intravenous infusion (30 minutes). Infusion should be completed within the period of stability of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g IV infusions after reconstitution and dilution as reflected in the table under

the section “Compatibility and Stability” presented above. The contents of the vials must be used within 15 minutes and thereafter any unused materials discarded.

Dosages:

General Information:

For infections caused by amoxycillin sensitive organisms the dosage is the same as that approved for amoxycillin as the clavulanic acid component does not contribute to the therapeutic effect.

Adult (intravenous):

For severe infections of the respiratory tract, urinary tract and skin and soft tissue requiring parenteral therapy: Initially SANDOZ CO-AMOXYCLAV 1,2 g vial containing the equivalent of 1000 mg amoxycillin and 200 mg clavulanic acid, can be administered intravenously 6 to 8 hourly by intravenous injection (2 minutes) or intravenous infusion (30 minutes) until the condition settles followed by oral therapy with SANDOZ CO-AMOXYCLAV 375 tablets at the recommended dose. If no response has occurred within 48 hours, therapy must be reviewed.

Intravenous treatment with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should not be extended beyond 10 days without review and the total daily administration of clavulanic acid should not exceed 800 mg. Treatment can be continued with SANDOZ CO-AMOXYCLAV 375 tablets orally where appropriate, after a satisfactory therapeutic response has been obtained.

Dosage guide:

Amoxycillin-Sensitive Organisms:

Product	***Upper respiratory***	***Lower respiratory tract infections***	***Urinary tract infections***	***Skin and soft tissue infections***

	tract infection			
Adults				
SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ and 20 mℓ	-	-	2 vials[1)] 6 to 8 hourly	2 vials[1)] 6 to 8 hourly
SANDOZ CO-AMOXYCLAV 1,2 g 20 mℓ and 50 mℓ	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly

Dosage guide:

Amoxycillin-Resistant Organisms:

Product	***Upper respiratory tract infections (otitis media)***	***Lower respiratory tract infections (bronchitis)***	***Urinary tract infections***	***Skin and soft tissue infections***
Adults				
SANDOZ CO-AMOXYCLAV 0,6 g 10 mℓ and 20 mℓ	-	-	2 vials[1)] 6 to 8 hourly	2 vials[1)] 6 to 8 hourly
SANDOZ CO-AMOXYCLAV 1,2 g 20 mℓ and 50 mℓ	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly	1 vial[1)] 6 to 8 hourly

[1)] Intravenous therapy should not be continued for longer than 10 days.

NOTE: Insufficient evidence exists at present to recommend an intravenous dosage in children.

Patients with renal impairment:

1 Each SANDOZ CO-AMOXYCLAV 0,6 g vial contains 0,5 mmoℓ potassium and 1,4 mmoℓ of sodium.

2 Each SANDOZ CO-AMOXYCLAV 1,2 g vial contains 1,0 mmoℓ of potassium and 2,8 mmoℓ of sodium.

As both the amoxycillin and the clavulanic acid components of SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g are excreted by the kidneys, accumulation of both may occur in patients with renal insufficiency. In these cases monitoring of the serum levels and reduction in the number of administrations of the suggested dosage may be required.

Experience 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***
> 30 mℓ/min	No dosage adjustment
10 to 30 mℓ/min	SANDOZ CO-AMOXYCLAV 1,2 g initially then 600 mg 12 hourly
< 10 mℓ/min	SANDOZ CO-AMOXYCLAV 1,2 g initially and then 600 mg daily

SIDE EFFECTS:

The most frequently reported adverse effects are diarrhoea, nausea, vomiting, indigestion, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes.

The incidence and severity of adverse effects, particularly nausea and diarrhoea, increased with the higher recommended dose and can be minimised by administering SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g at the start of a meal. In addition, as these symptoms are especially related to the potassium clavulanate component where these gastro-intestinal symptoms occur and a higher concentration of amoxycillin is required, consideration should be given to administering the additional amoxycillin separately.

The following adverse reactions have been reported and may occur with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g:

Hypersensitivity reactions:

Skin rashes, pruritus and urticaria, serum sickness-like syndrome, erythema multiforme, rare cases of Stevens-Johnson syndrome, hypersensitivity vasculitis, less frequently bullous exfoliative dermatitis and toxic epidermal necrolysis have been reported. Whenever such reactions occur, SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g should be discontinued. Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin (see “WARNINGS AND SPECIAL PRECAUTIONS”).

Interstitial nephritis can occur rarely.

Gastrointestinal reactions:

Nausea, vomiting, diarrhoea, gastritis, stomatitis, glossitis, black ‘hairy’ tongue, enterocolitis, mucocutaneous candidiasis and antibiotic-associated colitis (including pseudomembranous colitis and haemorrhagic colitis). If gastrointestinal reactions are evident, they may be reduced by taking SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g at the start of a meal.

Hepatic effects:

Hepatitis and cholestatic jaundice have been reported. The events may be severe and occur predominantly in adult or elderly patients. 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.

The hepatic effects are usually reversible. However, in extremely rare circumstances, death has been reported. These have almost always been cases associated with serious underlying disease or concomitant medication.

A moderate raise in aspartate transaminase (AST) and/ or alanine transaminase (ALT) has been noted in patients treated with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g, but the significance of these findings is unknown.

Renal effects:

Crystalluria has been reported

Haematological effects:

Haemolytic anaemia, reversible thrombocytopenia, thrombocytopenic purpura, eosinophilia, reversible leucopenia and agranulocytosis have been reported. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. A slight thrombocytosis was noted in less than 1 % of the patients treated with SANDOZ CO-AMOXYCLAV 0,6 g and 1,2 g. Prolongation of bleeding time and prothrombin time have also been reported less frequently. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly.

Central nervous system effects:

CNS effects have been seen rarely. These include reversible hyperactivity, dizziness, headache and convulsions. Convulsions may occur with impaired renal function or in those receiving high doses.

Miscellaneous:

Superficial tooth discolouration has been reported especially with the suspension and chewable tablet formulations. It can usually be removed by brushing.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage with amoxycillin is usually asymptomatic. However, gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water and electrolyte imbalance should be treated symptomatically.

Adequate fluid intake and urinary output must be maintained to minimise the possibility of crystalluria.

Amoxycillin 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 support that this compound may also be removed by haemodialysis.

IDENTIFICATION:

Sandoz Co-amoxyclav 0,6 g 10 mℓ and Sandoz Co-amoxyclav 0,6 g 20 mℓ:

A white to cream-tinged crystalline powder. When reconstituted a transient pink colour develops which becomes a clear straw coloured solution, free from foreign particles.

Sandoz Co-amoxyclav 1,2 g 20 mℓ and Sandoz Co-amoxyclav 1,2 g 50 mℓ:

A white to cream-tinged crystalline powder. When reconstituted a transient pink colour develops which becomes a clear straw coloured solution, free from foreign particles.

PRESENTATION:

Sandoz Co-amoxyclav 0,6 g 10 mℓ: 10 mℓ clear glass vial with bromo butyl rubber stopper and flip-off aluminium cap supplied in packs of 5 and 10.

Sandoz Co-amoxyclav 0,6 g 20 mℓ: 20 mℓ clear glass vial with bromo butyl rubber stopper and flip-off aluminium cap supplied in packs of 5 and 10.

Sandoz Co-amoxyclav 1,2 g 20 mℓ: 20 mℓ clear glass vial with bromo butyl rubber stopper and flip-off aluminium cap supplied in packs of 5 and 10.

Sandoz o-amoxyclav 1,2 g 50 mℓ: 50 mℓ clear glass vial with bromo butyl rubber stopper and flip-off aluminium cap supplied in packs of 5 and 10.

STORAGE INSTRUCTIONS:

Powder for injection: Store at or below 25 °C in a cool, dry place. Protect from light.

Reconstituted solution: Use immediately, within 15 minutes as an injection solution and within 60 minutes as an infusion solution. Discard any unused portion.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:

Sandoz Co-amoxyclav 0,6 g 10 mℓ: 38/20.1.2/0326

Sandoz Co-amoxyclav 0,6 g 20 mℓ: 38/20.1.2/0327

Sandoz Co-amoxyclav 1,2 g 20 mℓ: 38/20.1.2/0324

Sandoz Co-amoxyclav 1,2 g 50 mℓ: 38/20.1.2/0325

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Sandoz SA (Pty) Ltd[1]

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Spartan

Kempton Park

1619

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date of registration: 12 November 2004

Date of the most recent approval of the professional information: 14 March 2011

Additional countries registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Namibia	Sandoz Co-amoxyclav 0,6 g 20 mℓ	NS2	07/20.1.2/0114
	Sandoz Co-amoxyclav 1,2 g 20 mℓ	NS2	07/20.1.2/0115
Botswana	Sandoz Co-amoxyclav 0,6 g 20 mℓ	S2	BOT1101894
	Sandoz Co-amoxyclav 1,2 g 20 mℓ	S2	BOT1101893

Zambia	Sandoz Co-amoxyclav 0,6 g 20 mℓ	POM	039/008
	Sandoz Co-amoxyclav 1,2 g 20 mℓ	POM	039/009

ATC Code: J01CR02 - Combinations of penicillins, incl. beta-lactamase inhibitors

Name and address of manufacturer:

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Or

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