2D Matrix Code position may change as per Supplier's m/c requirement

MEROGRAM P1541179

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Summary of Product Characteristics

Name of the Medicinal Product: MEROGRAM 500 – Meropenem For Injection 500mg
MEROGRAM 1000 – Meropenem For Injection 1000mg

Qualitative and Quantitative Composition:

MEROGRAM 500:

Each vial contains: Meropenem trihydrate Ph.Eur. equivalent to 500 mg anhydrous meropenem
Sodium carbonate 104 mg

MEROGRAM 1000:

Each vial contains: Meropenem trihydrate Ph.Eur. equivalent to 1000 mg anhydrous meropenem
Sodium carbonate 208 mg

Pharmaceutical Form

Powder for Solution for Injection or Infusion.

MEROGRAM 500 is a white to pale yellow crystalline powder filled in 30ml Type-I, tubular, clear glass vial with stopper. After reconstitution clear colourless to yellow colour solution. Each vial contains 570.78 mg of Meropenem trihydrate which is equivalent to 500 mg of Meropenem anhydrous.

Each 500 mg vial contains 104 mg sodium carbonate which equates to approximately 2 mEq of sodium (approximately 45 mg).

MEROGRAM 1000 is a white to pale yellow crystalline powder filled in 40ml Type-I, tubular, clear glass vial with stopper. After reconstitution clear colourless to yellow colour solution. Each vial contains 1141.56 mg of Meropenem trihydrate which is equivalent to 1000 mg of Meropenem anhydrous.

Each 1000 mg vial contains 208 mg sodium carbonate which equates to approximately 4 mEq of sodium (approximately 90.2 mg).

Pharmacodynamics Mode of action

Meropenem exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram- positive and Gram-negative bacteria through binding to penicillin-binding proteins (PBPs).

Pharmacokinetic/Pharmacodynamic (PK/PD) relationship:

Similar to other beta-lactam antibacterial agents, the time that meropenem concentrations exceed

The MIC (T>MIC) has been shown to best correlate with efficacy. In preclinical models meropenem demonstrated activity when plasma concentrations exceeded the MIC of the infecting organisms for approximately 40 % of the dosing interval. This target has not been established clinically.

Mechanism of resistance

Bacterial resistance to meropenem may result from:

(1) decreased permeability of the outer membrane of Gram-negative bacteria (due to diminished production of porins)
(2) Reduced affinity of the target PBPs
(3) Increased expression of efflux pump components, and
(4) Production of beta lactamases that can hydrolysed carbapenems.

Localized clusters of infections due to carbapenem-resistant bacteria have been reported in the European Union.

There is no target-based cross-resistance between meropenem and agents of the quinolone, aminoglycoside, macrolide and tetracycline classes. However, bacteria may exhibit resistance to more than one class of antibacterial agents when the mechanism involved include impermeability and/or an efflux pump(s).

Breakpoints

European Committee on Antimicrobial Susceptibility Testing (EUCAST) clinical breakpoints for MIC testing are presented below.

EUCAST clinical MIC breakpoints for meropenem (2013-02-11, v 3.1)

Organism	Susceptible (S) (mg/l)	Resistant (R) (mg/l)
Enterobacteriaceae	≤2	>8
Pseudomonas spp.	≤2	>8
Acinetobacter spp.	≤2	>8
Streptococcus groups A, B, C and G	Note 6	Note 6
Streptococcus pneumoniae[1]	≤2	>2
Viridans group *streptococci*[2]	≤2	>2
Enterococcus spp.	--	--
Staphylococcus spp.	Note 3	Note 3
Haemophilus influenzae[1,2] *and Moraxella catarrhalis*[2]	≤2	>2
Neisseria meningitidis[2,4]	≤ 0.25	>0.25
Gram-positive anaerobes except *Clostridium difficile*	≤2	>8
Gram-negative anaerobes	≤2	>8
Listeria monocytogenes	≤ 0.25	>0.25
Non-species related breakpoints[5]	≤2	>8

[1] Meropenem breakpoints for Streptococcus pneumoniae and Haemophilus influenzae in meningitis are 0.25 mg/l (Susceptible) and 1 mg/l (Resistant).

[2] Isolates with MIC values above the susceptible breakpoint are very rare or not yet reported. The identification and antimicrobial susceptibility tests on any such isolate must be repeated and if the result is confirmed the isolate sent to a reference laboratory. Until there is evidence regarding clinical response for confirmed isolates with MIC values above the current resistant breakpoint, they should be reported resistant.

[3] Susceptibility of staphylococci to carbapenems is inferred from the cefoxitin susceptibility.

[4] Breakpoints relate to meningitis only.

[5] Non-species related breakpoints have been determined using PK/PD data and are independent of MIC distributions of specific species. They are for use only for organisms that do not have specific breakpoints. Non species related breakpoints are based on the following dosages: EUCAST breakpoints apply to meropenem 1000 mg x 3 daily administered intravenously over 30 minutes as the lowest dose. 2 g x 3 daily was taken into consideration for severe infections and in setting the I/R breakpoint.

[6] The beta-lactam susceptibility of streptococcus groups A, B, C and G is inferred from the penicillin susceptibility.

-- = Susceptibility testing not recommended as the species is a poor target for therapy with the drug. Isolates may be reported as R without prior testing.

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent in at least some types of infections is questionable.

The following table of pathogens listed is derived from clinical experience and therapeutic guidelines.

Commonly susceptible species
Gram-positive aerobes
Enterococcus faecalis$
Staphylococcus aureus (methicillin-susceptible) £
Staphylococcus species (methicillin-susceptible) including Staphylococcus epidermidis
Streptococcus agalactiae (Group B)
Streptococcus milleri group (S. anginosus, S. constellatus, and S. intermedius)
Streptococcus pneumoniae
Streptococcus pyogenes (Group A)
Gram-negative aerobes
Citrobacter freudii
Citrobacter k oseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Morganella morganii
Neisseria meningitidis
Proteus mirabilis
Proteus vulgaris
Serratia marcescens
Gram-positive anaerobes
Clostridium perfringens
Peptoniphilus asaccharolyticus
Peptostreptococcus species (including P. micros, P anaerobius, P. magnus)
Gram-negative anaerobes
Bacteroides caccae
Bacteroides fragilis group
Prevotella bivia
Prevotella disiens
Species for which acquired resistance may be a problem
Gram-positive aerobes
Enterococcus faecium$†
Gram-negative aerobes
Acinetobacter species
Burk holderia cepacia
Pseudomonas aeruginosa
Inherently resistant organisms
Gram-negative aerobes
Stenotrophomonas maltophilia
Legionella species
Other micro-organisms
Chlamydophila pneumoniae
Chlamydophila psittaci
Coxiella burnetii
Mycoplasma pneumoniae

$ Species that show natural intermediate susceptibility

£ All methicillin-resistant staphylococci are resistant to meropenem

† Resistance rate ≥ 50% in one or more EU countries.

Glanders and melioidosis: Use of meropenem in humans is based on in vitro B. mallei and B. pseudomallei susceptibility data and on limited human data. Treating physicians should refer to national and/or international consensus documents regarding the treatment of glanders and melioidosis.

Pharmacokinetic properties:

The mean plasma half-life is approximately 1 hour; the mean volume of distribution is approximately 0.25 l/kg (11-27 l) and the mean clearance is 287 ml/min at 250 mg falling to 205 ml/min at 2 g. Doses of 500, 1000 and 2000 mg doses infused over 30 minutes give mean Cmax values of approximately 23, 49 and 115 µg/ml respectively, corresponding AUC values were 39.3, 62.3 and 153 µg.h/ml. After infusion over 5 minutes Cmax values are 52 and 112 µg/ml after 500 and 1000 mg doses respectively. When multiple doses are administered with normal renal function, accumulation of meropenem does not occur.

Distribution

The average plasma protein binding of meropenem was approximately 2 % and was independent of concentration. After rapid administration (5 minutes or less) the pharmacokinetics are biexponential but this is much less evident after 30 minutes infusion. Meropenem has been shown to penetrate well into several body fluids and tissues: including lung, bronchial secretions, bile, cerebrospinal fluid, gynaecological tissues, skin, fascia, muscle, and peritoneal exudates.

Metabolism

Meropenem is metabolised by hydrolysis of the beta-lactam ring generating a microbiologically inactive metabolite. In vitro meropenem shows reduced susceptibility to hydrolysis by human dehydropeptidase-I (DHP-I) compared to imipenem and there is no requirement to co-administer a DHP-I inhibitor.

Elimination

Meropenem is primarily excreted unchanged by the kidneys; approximately 70 % (50 –75 %) of the dose is excreted unchanged within 12 hours. A further 28% is recovered as the microbiologically inactive metabolite. Faecal elimination represents only approximately 2% of the dose. The measured renal clearance and the effect of probenecid show that meropenem undergoes both filtration and tubular secretion.

Renal insufficiency

Renal impairment results in higher plasma AUC and longer half-life for meropenem. The AUC of the microbiologically inactive ring opened metabolite was also considerably increased in patients with renal impairment.

Dose adjustment is recommended for patients with moderate and severe renal impairment Meropenem is cleared by hemodialysis with clearance during hemodialysis being approximately 4 times higher than in anuric patients.

Hepatic insufficiency

No effect of liver disease on the pharmacokinetics of meropenem after repeated doses.

Adult patients

Intra-abdominal infection or pneumonia, showed a dependence of the central volume on weight and the clearance on creatinine clearance and age.

Paediatric population

The pharmacokinetics in infants and children with infection at doses of 10, 20 and 40 mg/kg showed Cmax values approximating to those in adults following 500, 1000 and 2000 mg doses, respectively. Approximately 60 % of the dose is excreted in urine over 12 hours as meropenem with a further 12 % as metabolite. Meropenem concentrations in the CSF of children with meningitis are approximately 20 % of concurrent plasma levels although there is significant inter-individual variability.

The pharmacokinetics of meropenem in neonates requiring anti-infective treatment showed greater clearance in neonates with higher chronological or gestational age with an overall average half-life of 2.9 hours. Monte Carlo simulation based on a population PK model showed that a dose regimen of 20 mg/kg 8 hourly achieved 60 %T>MIC for *P. aeruginosa* in 95 % of pre-term and 91 % of full-term neonates.

Elderly

Pharmacokinetic studies have shown a reduction in plasma clearance, which correlated with age-associated reduction in creatinine clearance, and a smaller reduction in non-renal clearance. No dose adjustment is required in elderly patients, except in cases of moderate to severe renal impairment.

Indication

MEROGRAM is indicated for treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to meropenem.

- Pneumonias and Nosocomial pneumonias
- Urinary Tract Infections
- Intra-abdominal Infections
- Gynaecological Infections, such as endometritis and pelvic inflammatory disease.
- Bacterial Meningitis
- Septicaemia
- Empiric treatment, for presumed infections in patients with febrile neutropenia, used as monotherapy or in combination with anti-viral or anti-fungal agents.

Merogram has proved efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infections.

Recommended Dose

Adults

The dosage and duration of therapy shall be established depending on type and severity of infection and the condition of the patient.

The recommended daily dosage is as follows:

500 mg IV every 8 hours in the treatment of pneumonia, UTI, gynaecological infections such as endometritis.

1 g IV every 8 hours in the treatment of hospital acquired pneumonias, peritonitis, presumed infections in febrile neutropenic patients, septicaemia.

In meningitis the recommended dosage is 2 g every 8 hours.

A dose of up to 2 g three times daily in adults and adolescents and a dose of up to 40 mg/kg three times daily in children may be particularly appropriate when treating some types of infections, such as nosocomial infections due to Pseudomonas aeruginosa.

Regular sensitivity testing is recommended when treating Pseudomonas aeruginosa infection.

There are limited safety data available to support the administration of a 2 g dose in adults as an intravenous bolus injection.

Dosage Schedule for Adults with Impaired Renal Function

Dosage should be reduced in patients with creatinine clearance less than 51 mL/min, as scheduled below. There are limited data to support the application of these dose adjustments for a unit dose of 2 g.

Creatinine Clearance(mL/min)	Dose (based on unit doses of 500 mg, 1 g, 2 g)	Frequency
26-50	one-unit dose	every 12 hours
10-25	one-half unit dose	every 12 hours
<10	one-half unit dose	every 24 hours

MEROGRAM is cleared by haemodialysis and haemofiltration; if continued treatment with MEROGRAM is necessary, it is recommended that the unit dose (based on the type and severity of infection) is administered at the completion of the haemodialysis procedure to restore therapeutically effective plasma concentrations.

There is no experience with the use of MEROGRAM in patients under peritoneal dialysis.

Dosage in Adults with Hepatic Insufficiency

No dosage adjustment is necessary in patients with hepatic insufficiency.

Elderly Patients

No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 mL/min.

Children

For children over 3 months and up to 12 years of age the recommended dose is 10 - 20 mg/kg every 8 hours depending on type and severity of infection, susceptibility of the pathogen and the condition of the patient. In children over 50 kg weight, adult dosage should be used.

In meningitis the recommended dose is 40 mg/kg every 8 hours.

Febrile episodes in neutropenic patients-the dose should be 20 mg/kg every 8 hours. There is no experience in children with renal impairment.

There are limited safety data available to support the administration of a 40 mg/kg dose in children as an intravenous bolus injection.

Method of Administration

MEROGRAM can be given as an intravenous bolus injection over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes using the specific available presentations.

MEROGRAM to be used for bolus intravenous injection should be constituted with sterile Water for Injections (5 mL per 250 mg Meropenem). This provides an approximate concentration of 50 mg/mL. Constituted solutions are clear, and colourless or pale yellow.

MEROGRAM for intravenous infusion may be constituted with compatible infusion fluids (50 to 200 mL).

Route of Administration

Intravenous (IV)

Contraindications

Hypersensitivity to the active substance or to any of the excipients. Hypersensitivity to any other carbapenem antibacterial agent.

Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins or cephalosporins).

Warnings and Precautions

The selection of meropenem to treat an individual patient should take into account the appropriateness of using a carbapenem antibacterial agent based on factors such as severity of the infection, the prevalence of resistance to other suitable antibacterial agents and the risk of selecting for carbapenem-resistant bacteria.

Enterobacteriaceae, Pseudomonas aeruginosa and *Acinetobacter* spp. resistance

Resistance to penems of *Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter* spp. varies across the European Union. Prescribers are advised to take into account the local prevalence of resistance in these bacteria to penems.

Hypersensitivity reactions

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta- lactams. Before initiating therapy with MEROGRAM, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, MEROGRAM must be discontinued immediately and appropriate alternative therapy instituted.

Black A/s: 254 x 470 mm Booklet Size: 35 x 60 mm

eugia Packaging Development	Product Name: **Merogram Injection**	Component: Leaflet	Item Code: P1541179	Date & Time: 01.12.2025 & 6:10 PM
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Team Leader: Ariff	Dimensions: 254 x 470 mm	No. of Colours : 01		
Initiator: Vijay				
Artist: Vision Graphic Designers	2D code: P1541179			Sign / Date
Additional Information :				

Antibiotic-associated colitis

Antibiotic-associated colitis and pseudomembranous colitis have been reported with nearly all anti-bacterial agents, including meropenem, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea during or subsequent to the administration of meropenem. Discontinuation of therapy with meropenem and the administration of specific treatment for Clostridium difficile should be considered. Medicinal products that inhibit peristalsis should not be given.

Seizures

Seizures have infrequently been reported during treatment with carbapenems, including meropenem.

Hepatic function monitoring

Hepatic function should be closely monitored during treatment with meropenem due to the risk of hepatic toxicity (hepatic dysfunction with cholestasis and cytolysis).

Use in patients with liver disease: patients with pre-existing liver disorders should have liver function monitored during treatment with meropenem. There is no dose adjustment necessary.

Direct antiglobulin test (Coombs test) seroconversion

A positive direct or indirect Coombs test may develop during treatment with meropenem.

Concomitant use with valproic acid/sodium valproate/valpromide

The concomitant use of meropenem and valproic acid/sodium valproate/valpromide is not recommended.

Paediatric population

Meropenem is licensed for children over 3 months of age. There is no evidence of an increased risk of any adverse drug reaction in children based on the limited available data. All reports received were consistent with events observed in the adult population.

Meropenem contains sodium.

MEROGRAM 500 mg: This medicinal product contains approximately 2.0 mEq of sodium per 500 mg dose which should be taken into consideration by patients on a controlled sodium diet.

MEROGRAM 1000 mg: This medicinal product contains approximately 4.0 mEq of sodium per 1000 mg dose which should be taken into consideration by patients on a controlled sodium diet.

Interactions with other Medicaments

No specific medicinal product interaction studies other than probenecid were conducted.

Probenecid competes with meropenem for active tubular secretion and thus inhibits the renal excretion of meropenem with the effect of increasing the elimination half-life and plasma concentration of meropenem. Caution is required if probenecid is co-administered with meropenem.

The potential effect of meropenem on the protein binding of other medicinal products or metabolism has not been studied. However, the protein binding is so low that no interactions with other compounds would be expected on the basis of this mechanism.

Decreases in blood levels of valproic acid have been reported when it is co-administered with carbapenem agents resulting in a 60-100 % decrease in valproic acid levels in about two days. Due to the rapid onset and the extent of the decrease, co-administration of valproic acid/sodium valproate/valpromide with carbapenem agents is not considered to be manageable and therefore should be avoided.

Oral anti-coagulants

Simultaneous administration of antibiotics with warfarin may augment its anti-coagulant effects. There have been many reports of increases in the anti-coagulant effects of orally administered anticoagulant agents, including warfarin in patients who are concomitantly receiving antibacterial agents. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of the antibiotic to the increase in INR (international normalized ratio) is difficult to assess. It is recommended that the INR should be monitored frequently during and shortly after coadministration of antibiotics with an oral anti-coagulant agent.

Pregnancy and Lactation

There are no or limited amount of data from the use of meropenem in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use of meropenem during pregnancy.

Breast-feeding

Small amounts of meropenem have been reported to be excreted in human milk. Meropenem should not be used in breast-feeding women unless the potential benefit for the mother justifies the potential risk to the baby.

Side Effects

Summary of the safety profile

Meropenem-related adverse reactions most frequently reported were diarrhoea, rash, nausea/vomiting and injection site inflammation. The most commonly reported meropenem- related laboratory adverse events were thrombocytosis and increased hepatic enzymes.

Table 1

System Organ Class	Frequency	Event
Infections and infestations	Uncommon	oral and vaginal candidiasis
	Common	thrombocythaemia
Blood and lymphatic system disorders	Uncommon	eosinophilia, thrombocytopenia, leucopenia, neutropenia, agranulocytosis, haemolytic anemia
Immune system disorders	Uncommon	angioedema, anaphylaxis
Nervous system disorders	Common	headache
	Uncommon	paresthesia
	Rare	convulsions
Gastrointestinal disorders	Common	diarrhoea, vomiting, nausea, abdominal pain
	Uncommon	antibiotic-associated colitis
Hepatobiliary disorders	Common	transaminases increased, blood alkaline phosphatase increased, blood Lactate dehydrogenase increased.
	Uncommon	blood bilirubin increased
Skin and subcutaneous tissue disorders	Common	rash, pruritis
	Uncommon	urticaria, toxic epidermal necrolysis, Stevens Johnson syndrome, erythema Multiforme.
	Not known	Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS Syndrome)
Renal and urinary disorders	Uncommon	blood creatinine increased, blood urea increased
General disorders and administration site conditions	Common	inflammation, pain
	Uncommon	Thrombophlebitis, pain at the injection site

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Symptoms and Treatment of Overdose

Relative overdose may be possible in patients with renal impairment if the dose is not adjusted as described.

Limited post-marketing experience indicates that if adverse reactions occur following overdose, they are consistent with the adverse reaction profile as described, are generally mild in severity and resolve on withdrawal or dose reduction.

Symptomatic treatments should be considered.

In individuals with normal renal function, rapid renal elimination will occur.

Hemodialysis will remove meropenem and its metabolite.

Effects on Ability to Drive and Use machine

No studies on the effect on the ability to drive and use machines have been performed. However, when driving or operating machines, it should be taken into account that headache, paresthesia and convulsions have been reported for meropenem.

Preclinical Safety data:

Not applicable

Instructions for Use: <u>After reconstitution</u>:

Intravenous bolus injection administration

A solution for bolus injection is prepared by dissolving the drug product meropenem in sterile water for injection to a final concentration of 50 mg/ml.

Chemical and physical in-use stability for a prepared solution for bolus injection has been demonstrated up to 3 hours at controlled room temperature (15-25°C) or up to 8 hours under refrigerated conditions (2-8°C). From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately.

If not used immediately in-use storage times and conditions are the responsibility of the user.

Intravenous infusion administration

A solution for infusion is prepared by dissolving the drug product meropenem in either 0.9% sodium chloride solution for infusion or 5% glucose (dextrose) solution for infusion to a final concentration of 1 to 20 mg/ml.

Chemical and physical in-use stability for a prepared solution for infusion using 0.9% sodium chloride solution has been demonstrated for 6 hours at controlled room temperature (15- 25°C) or upto12 hours under refrigerated conditions (2-8°C). In this case, the prepared solution if stored under refrigeration (i.e. 2-8°C) should be used within 1 hour after it has left the refrigerator.

From a microbiological point of view, unless the method of opening/reconstitution/dilution precludes the risk of microbiological contamination, the product should be used immediately. If not used immediately in-use storage times and conditions are the responsibility of the user.

Reconstituted solution of meropenem in 5% glucose (dextrose) solution should be used immediately, i.e. within 30 minutes following reconstitution.

Do not freeze the reconstituted solution.

Special precautions for disposal and other handling

Injection

Meropenem to be used for bolus intravenous injection should be constituted with sterile water for injection.

Infusion

For intravenous infusion meropenem vial may be directly constituted with 0.9% sodium chloride or 5% glucose (dextrose) solutions for infusion.

The product should be inspected visually for particulate matter, damage to the container or discolouration (solution should be colourless to pale yellow) prior to administration. Discard the product if such defects are observed.

Each vial is for single use only.

Standard aseptic techniques should be used for solution preparation and administration. The solution should be shaken before use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Storage Condition

Do not store above 30°C.

Do not freeze the reconstituted solution.

Nature and contents of container

Meropenem 500 mg:

674.78mg powder in a 30ml Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminium seals having taxim blue colour polypropylene discs).

Meropenem 1000 mg:

1349.56 mg powder in a 40ml Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminum seals having white colour polypropylene discs).

The medicinal product is supplied in pack sizes of Mono Vial or 10 Vials.

Shelf Life

24 months

Therapeutic Code

ATC Code: J01DH02

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