1. NAME OF PRODUCT

TAZOCIN® 2 g / 0.250 g lyophilized powder for injectable solution
TAZOCIN® 4 g / 0.500 g lyophilized powder for intravenous infusion
(Piperacillin/Tazobactam)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of TAZOCIN 2 g/0.250 g contains:
Piperacillin sodium (equiv. to piperacillin 2 g) 2085 mg
Tazobactam sodium (equiv. to tazobactam 250 mg) 268.3 mg
Excipients:
Disodium Edetate Dihydrate 0.5mg
Citric Acid Monohydrate (equiv. to 72 mg of free acid) 78.75 mg
Each vial of TAZOCIN 4 g/0.500 g contains:
Piperacillin sodium (equiv. to piperacillin 4 g) 4170 mg
Tazobactam sodium (equiv. to tazobactam 500 mg) 536.6 mg
Excipients:
Disodium Edetate Dihydrate 1 mg
Citric Acid Monohydrate (equiv. to 144 mg of free acid) 157.5 mg

Each vial of Tazocin contains a total of 2.79 mEq (64 mg) of sodium per gram of piperacillin.

3. PHARMACEUTICAL FORM AND ADMINISTRATION METHOD

TAZOCIN 2 g/0.250 g: lyophilized powder for intravenous and intramuscular injectable solution.

TAZOCIN 4 g/0.500 g: lyophilized powder for intravenous infusion.

4. CLINICAL INFORMATION

4.1 Indications

TAZOCIN is indicated for the treatment of the following infections with proven or suspected presence of susceptible microorganisms: infections of the lower respiratory tract, infections of the urinary tract (complicated and not), intra-abdominal infections, skin infections, bacterial septicemia, polymicrobial infections.
TAZOCIN is indicated for the treatment of mixed bacterial infections shown or those assumed to be caused by aerobic and anaerobic microorganisms (intra-abdominal, skin, lower respiratory tract).
Although TAZOCIN is indicated only for the specific conditions indicated above, it may also be used for any infections caused by piperacillin-susceptible bacteria without requiring the addition of other antibiotics in presence of β-lactamase producing organisms.
TAZOCIN is especially useful in the treatment of mixed infections and, because of its wide spectrum of activity, can adequately cover the patient during presumptive therapy while waiting for susceptibility results.
In particular it is indicated for the presumptive monotherapy of infections in adult patients with febrile neutropenia: anyhow, the treatment must be adjusted in function of culture and bacteriological results.
TAZOCIN acts synergically with aminoglycosides against several strains of *Pseudomonas aeruginosa*. This combination, that involves the administration of the drugs at full dosage, is effective, especially in immunodepressed patients; anyhow, the treatment must be adjusted in function of culture and bacteriological results.

Children aged under 12
In hospitalized children aged between 2 and 12, TAZOCIN is indicated for the treatment of intra-abdominal infections, including appendicitis complicated by rupture or abscess, peritonitis and biliary tract infections. The use of the drug for this indication in children aged under 2 has not been established.

4.2 Dosage and administration

TAZOCIN 2 g/0.250 g may be administered either by intramuscular injection or by intravenous injection or slow intravenous infusion over 20-30 minutes. TAZOCIN 4 g/0.500 g may be administered only by slow intravenous infusion or phlebocylsis.

DOSAGE IN PATIENTS OVER 12 YEARS OF AGE
The usual dosage for adults and for juveniles aged 12 and up with normal renal function is 2 g/0.250 g of piperacillin/tazobactam every 12 hours by intramuscular injection; via intravenous administration dosage ranges from a minimum of 2 g/0.250 g up to a maximum of 4 g/0.5 g of piperacillin/tazobactam administered every 6, 8 or 12 hours. When TAZOCIN is used in the presumptive monotherapy of infections in adult patients with febrile neutropenia, the suggested dosage is 4 g/0.500 g of TAZOCIN every 6-8 hours administered intravenously.

HOSPITALIZED CHILDREN WITH INTRA-ABDOMINAL INFECTIONS
In the case of children aged between 2 and 12, weighing up to 40 kg and with normal kidney function, the suggested dosage per kilogram of body weight is 100 mg of piperacillin/12.5 mg of tazobactam every 8 hours, administered by slow intravenous infusion. In the case of children aged between 2 and 12, weighing more than 40 kg and with normal kidney function, the suggested daily dosage is 4g of piperacillin/0.5 g of tazobactam every 8 hours, administered by slow intravenous infusion.
Therapy duration should be adjusted according to infection severity and to the patient's clinical and bacteriological response. It is recommended that the therapy be protracted for at least 5 days, up to a maximum of 14 days, considering that administration should continue for another 48 hours after resolution of all clinical signs and symptoms.

Children aged under 2
Since no data are available for children aged under 2, TAZOCIN is not recommended for this age group.

Renal insufficiency in subjects aged over 12
In patients with renal insufficiency, intravenous administration, and the interval between administrations, must be adjusted based on the degree of residual kidney function.
Suggested daily doses are the following:
In patients with renal insufficiency or in hemodialysis, the intravenous dose must be adapted to the degree of insufficiency of renal function.

Creatinine Clearance (ml/min)	Recommended TAZOCIN dosage
> 40	No dosage adjustment is necessary
20 - 40	Maximum dosage suggested: 4 g/0.5 g every 8 hours
< 20	Maximum dosage suggested: 4 g/0.5 g every 12 hours

For patients on hemodialysis, the maximum daily dosage is 8 g/1 g of TAZOCIN. Because hemodialysis removes from 30% to 50% of piperacillin in 4 hours, patients on hemodialysis should receive a 2 g/0.250 g vial following each dialysis period. For patients with renal impairment and renal insufficiency, measurement of serum levels of piperacillin and tazobactam will provide additional guidance for adjusting dosage.

Renal insufficiency in children aged between 2 and 12.
Since the pharmacokinetics of piperacillin/tazobactam have not been studied in pediatric patients with renal insufficiency, changes of the dosage indicated in the following table should be considered as purely indicative.
Each patient should be closely monitored for the onset of any signs of drug toxicity. Drug dosage and intervals then should be consequently adjusted.

In general, the following dosage adjustments are recommended for pediatric patients with renal insufficiency aged between 2 and 12:

Creatinine Clearance (ml/min)	Recommended dosage of TAZOCIN
> 50 ml/min	(100 mg piperacillin/12.5 mg tazobactam)/kg every 8 hours, by slow intravenous infusion
≤ 50 ml/min	(70 mg piperacillin/8.75 mg tazobactam)/kg every 8 hours, by slow intravenous infusion

Patients with hepatic impairment
In patients with altered hepatic function no dosage adjustment is required.

IV administration
Co-administration of piperacillin/tazobactam with aminoglycosides
Considering the inactivation in vitro of the aminoglycosides by the beta-lactamic antibiotics, the separate administration of piperacillin/tazobactam and of the aminoglycosides is recommended.
If a concomitant therapy with aminoglycosides should be considered appropriate, the piperacillin/tazobactam and the aminoglycosides should be reconstituted and diluted separately.
In the case of administration intramuscularly, piperacillin/tazobactam and the aminoglycosides should be reconstituted and administered separately in different injection sites.
In the case of co-administration being preferred, the formulation in vials of piperacillin/tazobactam with EDTA is compatible with the simultaneous co-administration by infusion using a Y -site infusion only for the following aminoglycosides and under the following conditions:

Aminoglyco-sides	Piperacillin/ tazobactam (grams) dose	Piperacillin/ Tazobactam Volume of diluent (ml)	Aminoglyco-sides Concentration interval (mg/ml)	Compatible diluents
Amikacin	2.25–4.5	50,100,150	1.75 –7.5	0.9% sodium chloride or dextrose 5%
Gentamycin	2.25-4.5	100,150	0.7 – 3.32	0.9% sodium chloride

The dose of aminoglycosides should be calculated considering the patient's weight, the state of the infection (serious or endangering life) and kidney function (creatinine clearance).
The compatibility of piperacillin/tazobactam with the other aminoglycosides has not been established. Compatibility for co-administration using a Y -site infusion has been established only for the concentrations and the diluents of amikacin and gentamycin with the dosages of piperacillin/tazobactam indicated in the above-mentioned table.
The simultaneous co-administration using a Y -site infusion made in any way other than that mentioned heretofore may cause an inefficiency of the aminoglycoside by piperacillin/tazobactam.

Duration of therapy
For acute infections, treatment using Tazocin should last at least 5 days and should be continued for another 48 hours after resolution of clinical symptoms or fever.

INSTRUCTIONS FOR RECONSTITUTION AND DILUTION
Intravenous administration
Reconstitute the product with the quantity of solvent indicated in the following table, using one of the compatible solutions listed below. Shake until completely dissolved. Shaking constantly, the reconstitutions should take place within 10 minutes.

Vial content (piperacillin/tazobactam)	*Quantity of solvent to be added*
TAZOCIN 2 g/0.250 g	10 mL
TAZOCIN 4 g/0.5 g	20 mL

Compatible solutions
Sterile water for injections, Saline solution, Water/Benzyl alcohol solution for injections, Bacteriostatic saline/Benzyl alcohol solution, Water/Parabens solution for injections, Bacteriostatic saline/Parabens solution, Dextrose 5% & Ringer lactate solution

Pull up into a syringe the diluted solution from the vial. If reconstitution has been carried out as described, the solution in the syringe shall contain the quantity of piperacillin and tazobactam declared on the label.
The reconstituted solution can be further diluted to the required volume (50-150 mL) using a compatible intravenous diluent solution listed below:
Sterile water for injections (*), Saline solution, Glucose solution 5%, Dextran 6% in saline solution

(*) Maximum recommended volume of sterile water for injections per dose is 50 mL.

Intramuscular administration
TAZOCIN 2.250 must be reconstituted using 4 mL of a compatible solution.
Do not exceed the dosage of 2 g/0.250 g of piperacillin/tazobactam per injection site.
DO NOT ADMINISTER TAZOCIN 4 g/0.500 g BY INTRAMUSCULAR INJECTION.

Incompatibility
Whenever TAZOCIN is to be administered together with other antibiotics (such as aminoglycosides, for example), the drugs should be administered separately.
The in vitro admixture of TAZOCIN with an aminoglycoside may cause substantial deactivation of the action of the aminoglycoside. However it has been demonstrated that amikacin and gentamycin are compatible in vitro with reformulated Tazocin containing EDTA in certain diluents at specific concentrations (see section 4), but only for simultaneous Y-site infusion.
In the case of intramuscular administration, piperacillin/tazobactam and aminoglycosides should be reconstituted and administered separately in different injection sites.
TAZOCIN should not be mixed with other drugs in the same syringe or infusion bottle, since compatibility has not been established.
TAZOCIN should not be used with solutions containing sodium bicarbonate alone because of its chemical instability.
TAZOCIN should not be added to haematic products or to albumine hydrolysates.

4.3 Contraindications

Hypersensitivity to penicillins, and or cephalosporins and other beta-lactamase inhibitors.

4.4 Special warnings and precautions for use

WARNINGS
As with other antibiotics, the prolonged use of penicillins may favor the development of penicilin-resistant microorganisms, including fungi, requiring the adoption of adequate therapy measures.
Bleeding manifestations have been occasionally reported in several patients treated with beta-lactam antibiotics. These reactions have sometimes been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time, and are more likely to occur in patients with renal insufficiency. If bleeding manifestations occur, Tazocin should be discontinued and appropriate therapy instituted.
Rare cases of pseudomembranous colitis has been observed correlatable to the use of the antibiotic.
The symptoms of antibiotic-induced pseudomembranous colitis may be severe and persistent diarrhea that may become life-threatening.
The onset of pseudomembranous colitis symptoms may occur during or following antibacterial therapy.
It is important to consider this diagnosis in the case of significant diarrhea or colitis during therapy with Tazocin. Mild cases usually respond to drug discontinuation. In more severe cases; however, the use of fluids, electrolytes, protein supplements and, if required, treatment with oral vancomycin or oral teicoplanin are recommended. Peristalsis-inhibiting preparations are contraindicated.

Children aged under 2
Due to the lack of data concerning children aged under 2, the use of Tazocin for such patients is not recommended.

PRECAUTIONS

During prolonged high dose therapy, periodic assessments of hematopoietic, kidney and liver function should be performed.
This product contains 2.79 mEq (64 mg) of sodium per gram of piperacillin which may contribute in increasing the patient's total sodium intake.
Since hypokalemia may occur in patients with low potassium reserves or in patients concomitantly taking potassium-reducing drugs, periodical testing for the electrolyte is recommended.
Serious and sometimes fatal hypersensitivity and anaphylactic reactions have been reported in patients treated with penicillins, including piperacillin/tazobactam compounds.
These reactions are more likely to occur in individuals with a history of hypersensitivity to multiple allergens, of asthma, hay fever and urticaria. Cross-allergy is possible with penicillin G., semi-synthetic penicillins and cephalosporins. Careful history-taking regarding prior hypersensitivity to penicillins, cephalosporins and other allergens is therefore recommended before starting therapy with piperacillin/tazobactam.
If an allergic reaction occurs, the treatment should be discontinued and appropriate therapy instituted (with vasopressor amines, antihistamines, corticosteroids) or, in the case of hypersensibility reactions, immediate therapy with adrenaline, epinephrine or other suitable emergency measures.
As with other penicillins, in the case of intravenous administration of higher than recommended doses, patients may experience neuromuscular excitability or convulsions.
Leukopenia and neutropenia may occur, especially after prolonged therapy.
Therefore, the hemopoietic should be checked frequently.

Use in patients with kidney impairment:
In patients with kidney impairment or undergoing dialysis, the intravenous dosage should be adjusted to the degree of kidney insufficiency.

4.5 Interactions with other drugs

The contemporary administration of Probenecid with piperacillin/tazobactam causes a longer half-life and a lowering of renal clearance both of piperacillin and of tazobactam; however, the plasma concentrations of both drugs remain unaltered.
No interactions have been observed between Tazocin and Vancomycin or Tobramycin.
During the simultaneous administration of high doses of heparin, oral anti-coagulants and other drugs capable of affecting the blood coagulation system and/or the thrombocyte function, coagulation parameters should be tested more frequently and monitored regularly.
When used contemporarily with vecuronium, piperacillin may prolong the neuromuscular blocking action of vecuronium. Due to their similar mechanism of action, it is expected that the neuromuscular blockade produced by any of the non-depolarizing muscle relaxants could be prolonged in the presence of piperacillin.
Piperacillin may reduce the clearance of methotrexate. Serum methotrexate levels should therefore be monitored frequently to prevent methotrexate-induced toxicity.

Interference with laboratory tests and other diagnostic tests
As per other penicillins, the administration of Tazocin may cause a false-positive reaction regarding glucose in the urine; this happens when the "reduction of copper test" is used. It is recommended the use of a test for the glucose, based on enzymatic reaction of glucose oxydase is recommended.

There have been reports of positive test results using the Bio-Rad Laboratories Platelia Aspergillus EIA test in patients receiving piperacillin/tazobactam injection who were subsequently found to be free of Aspergillus infection. Non-Aspergillus polysaccharide and polyfuranose cross-reactions have been observed with the Platelia Aspergillus EIA test of the Bio-Rad Laboratories. Accordingly, positive results in patients treated with piperacillin/tazobactam need to be interpreted with care and confirmed by other diagnostic means.

4.6 Use during pregnancy and nursing

Studies conducted in rats and mice have not disclosed any evidence for an embryotoxic or teratogenic potential of the piperacillin/tazobactam association. There are, however, no adequate and well-controlled studies with the piperacillin/tazobactam combination or with piperacillin or tazobactam alone in pregnant women. Piperacillin and tazobactam cross the placenta.
This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the pregnant woman and to the fetus.
Piperacillin is excreted in low concentrations into human milk; tazobactam levels in human milk have not been studied. This drug should be used during nursing only if the potential benefit justifies the potential risk to the woman and to the infant.

4.7 Effects on ability to drive and use of machinery

The product does not interfere with driving and machine handling capabilities.

4.8 Adverse reactions

Adverse reactions are listed by target organs and systems and are subdivided by decreasing order of frequency as follows:

- very common = reactions occurring with a ≥10% frequency
- common = reactions occurring with a ≥ 1% frequency
- uncommon = reactions occurring with a ≥ 0.1% to < 1% frequency
- rare = reactions occurring with a ≥0.01% to < 0.1% frequency
- very rare = reactions occurring with a < 0.01% frequency

Infections and infestations
Uncommon: superinfection by Candida.

Blood and lymphatic system
Uncommon: leukopenia, neutropenia, thrombocytopenia.
Rare: anemia, bleeding events (including purpura, epistaxis, prolongation of bleeding time), eosinophilia, hemolytic anemia.
Very rare: agranulocytosis, Pancytopenia, protracted partial thromboplastin time, protracted prothrombin time, thrombocytosis.

Immune system disorders
Uncommon: hypersensitivity reactions.
Rare: anaphylactic/anaphylactoid (including shock) reactions.

Metabolic and nutritional disorders
Very rare: decrease in blood albumin, decreased glycemia, decreased total blood protein, hypokalemia.

Nervous system disorders
Uncommon: headache, insomnia.

Vascular disorders
Uncommon: hypotension, phlebitis, thrombophlebitis.
Rare: flushing.

Gastro-intestinal Disorder
Common: diarrhea, nausea, vomiting.
Uncommon: constipation, dyspepsia, jaundice, stomatitis.
Rare: stomach pain, pseudomembranous colitis.

Hepato-biliary disorders
Uncommon: increased alanine aminotransferase, increased aspartate aminotransferase.
Rare: increased bilirubin, increased blood alkaline phosphatase, increased gammaglutamyltransferase.

Cutaneous and subcutaneous disorders
Common: rash.
Uncommon: itching, urticaria.
Rare: pemphigus, multiform erythema.
Very rare: Stevens-Johnson syndrome, toxic epidermal necrolysis.

Musculoskeletal, connective tissue and bone disorders
Rare: arthralgia.

Kidney and urinary disorders
Uncommon: increased blood creatinine.
Rare: interstitial nephritis, kidney failure.
Very rare: increased uremia.

General and injection site disorders
Uncommon: fever, reaction at injection site.
Rare: rigidity.

Therapy with piperacillin has been associated with increased occurrence of fever and rash in patients suffering from cystic fibrosis.

4.9 Overdosage

There have been postmarketing reports of overdose with Tazocin. The majority of those events experienced, including nausea, vomiting, and diarrhea, have also been reported with the usual recommended dosages. Patients may experience neuromuscular excitability or convulsions if higher than recommended doses are given intravenously (particularly in the presence of renal failure).
Both piperacillin and tazobactam are removed from the body during hemodialysis.
The dosages for dialysis patients are indicated in paragraph 4.2 "Dosage and administration".

Children aged between 2 and 12
See paragraph 4.2 "Dosage and administration".

Patients with liver function disorders:
No dosage adjustment is required for patients with liver function disorders.
The half-life of piperacillin and of tazobactam increase by about 25% and 18%, respectively, in patients with cirrhosis of the liver when compared to healthy subjects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Microbiology
Tazocin is a new injectable antibacterial medication for intravenous and intramuscular use. Its active ingredients are piperacillin sodium and tazobactam, an irreversible bacterial beta-lactamase inhibitor.
Piperacillin is a semi-synthetic penicillin belonging to the group of acylureidopenicillins, featuring wide spectrum antibacterial action extending both to gram-positive and to gram-negative bacteria, anaerobes included.
Tazobactam, a penicillin derivative, is a powerful irreversible inhibitor of many bacterial, plasmid and chromosomal beta-lactamases, generally capable of causing resistance to penicillins, and cephalosporins, including third generation cephalosporins.
The presence of tazobactam in the combination with piperacillin enhances the drug's wide antibacterial spectrum while extending its antimicrobial activity against a large number of beta-lactamase producing strains of bacteria, including staphylococci.
The following pathogens have proved susceptible in vitro to the piperacillin/tazobactam combination:

Gram-positive beta-lactamase producing and non producing aerobes, such as strains of streptococci (*S. pneumoniae, S. pyogenes, S. bovis, S. agalactiae, S. viridans*, C group, G group), enterococci (*E. faecalis, E. faecium*), Staphylococcus aureus (not methicillin-resistant S. aureus), S. saprophyticus, S. epidermidis (coagulase-negative staphylococci), *Corynetacterium, Listeria monocytogenes, Nocardia spp.*

Gram-negative beta-lactamase producing and non producing aerobes, such as *Escherichia coli, Citrobacter spp.* (including *C. freundii, C. diversus*), *Klebsiella spp.* (including *K. oxytoca, K. pneumoniae*), *Enterobacter spp.* (including *E. cloacae, E. aerogenes*), *Proteus vulgaris, Proteus mirabilis, Providencia rettgeri, Providencia stuartii, Pesoumonas shigelloides*

- Shigelloides, Morganella morganii, Serratia spp. (including *S. marcescens, S. liquifaciens*), *Salmonella spp., Shigella spp., Pseudomonas aeruginosa and other Pseudomonas spp.* (including *P. capacia, P. fluorescens*), *Xanthomonas maltophilia, Neisseria gonorrhoeae, Neisseria meningitidis, Moraxella spp.* (including *Branhamella catarrhalis*), *Acinetobacter spp., Haemophilus influenzae, H. parainfluenzae, Pasteurella multocida, Yersinia spp., Camphylobacter spp., Gardnerella vaginalis.*

Anaerobes beta-lactamase producing and non producing, such as *Bacteroides spp.* (including *B. bivius, B. disiens, B. capillosus, B. melaninogenicus, B. oralis*), *Bacteroides fragilis* (including *B. fragilis, B. vulgatus, B. distasonis, B. ovatus, B. thetaiotaomicron, B. uniformis, B. asaccharolyticus*, as well as *Peptostreptococcus spp., Fusobacterium spp., Eubacterium group, Clostridium spp.* (including *C. difficile, C. perfrigens, Veillonella spp.* and *Actinomyces spp.*

5.2 Pharmacokinetics properties

Bioavailability and absorption:
Tazocin is completely absorbed immediately following both intravenous and intramuscular administration, becoming 71% (piperacillin) and 84% (tazobactam) bioavailable.
Peak plasma concentrations of Tazocin are attained immediately after completion of intravenous infusion and 40-50 minutes after intramuscular administration.
Plasma protein binding reaches approx. 30%.
This means a large share of the drug becomes immediately available for distribution into the blood and body tissues, ready to perform its antibacterial activity. In fact, Tazocin is widely distributed into all body tissues and fluids, and especially into the intestinal mucosa, the gallbladder, the lungs, bile and bone. Mean tissue concentrations range from 50% to 100% of plasma concentrations.

Excretion:
TAZOCIN is excreted rapidly by the kidneys via glomerular filtration and tubular secretion. A high percentage of the administered dose (69%) is excreted unchanged in the urine.

Patients with renal impairment:
Individuals aged over 12

Dosage adjustment is recommended when creatinine clearance is lower than 40 mL/min (see paragraph 4.2 "Dosage and administration").
Both piperacillin and tazobactam are removed from the body during hemodialysis.
The dosages for dialysis patients are indicated in paragraph 4.2 "Dosage and administration".

Children aged between 2 and 12
See paragraph 4.2 "Dosage and administration".

Patients with liver function disorders:
No dosage adjustment is required for patients with liver function disorders.
The half-life of piperacillin and of tazobactam increase by about 25% and 18%, respectively, in patients with cirrhosis of the liver when compared to healthy subjects.

5.3 Preclinical safety data

LD_{50} in mice (intravenously) is 4.5 g for piperacillin and 0.5625 g for tazobactam; the combination drug has not shown any teratogenic effects and has not affected the fertility rates of the animals tested.
No carcinogenic testing was conducted on piperacillin, on tazobactam or on the combination drug.
TAZOCIN was negative in microbial mutagenicity assays.
TAZOCIN was negative in the unscheduled DNA synthesis (UDS) test.
TAZOCIN was negative in a mammalian point mutation (Chinese hamster ovary cell HPRT) assay.
TAZOCIN was negative in a mammalian cell (BALB/c-3T3) transformation assay.
In vivo, TAZOCIN did not induce chromosomal aberrations in rats dosed intravenously.

6. PHARMACEUTICAL DATA

6.1 List of Excipients

Tazocin 2g+0.250 g / 4 ml powder and solvent for injectable solution
Powder bottle : Dehydrated disodium ededate , monohydrated citric acid
Solvent vial: Lidocaine hydrochloride , water for injectable preparation

Tazocin 4g+0.500 g powder and solvent for solution for infusion
Powder bottle : Dehydrated disodium ededate , monohydrated citric acid

Tazocin 4g+0.500 g powder and solvent for solution for infusion - 12 bottles
Powder bottle : Dehydrated disodium ededate , monohydrated citric acid

6.2 Incompatibility

See paragraphs 4.2 and 4.5.

6.3 Shelf-life and stability

Keep out of the reach and sight of children.
Do not use the product after the expiry date which is stated on the carton / Vial label after EXP:. The expiry date refers to the last day of that month
After reconstitution the solution must be administered immediately.
Unused solution must be discarded.
Storage at no more than 25°C

6.4 Special storage precautions

See paragraph 6.3.

6.5 Type of container and packaging

Primary container material: Type I glass vial, in compliance with O.P. current edition
TAZOCIN 2 g/0.250 g: 1 vial containing 2 g/0.250 g of piperacillin/tazobactam
TAZOCIN 4 g/0.5 g: 1 vial containing 4 g/0.500 g of piperacillin/tazobactam

6.6 Instructions for use

See paragraph 4.2 "Dosage and administration".

7. NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

Marketing Authorization Holder:
Wyeth Lederle S.p.A., Aprilia, Italy

Manufactured by:
Wyeth Lederle S.p.A, Catania, Italy

8. Date of Revision

June 2009

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The Doctor and Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

KEEP ALL MEDICAMENTS OUT OF REACH AND SIGHT OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

Wyeth*

*** Trademark**