TAZOBACT® 2 g / 250 mg & 4 g / 500 mg

Piperacillin-Tazobactam 2 g / 250 mg & 4 g / 500 mg
Powder for injectable preparation I.V. way (Infusion)

FORMS AND PRESENTATIONS:
TAZOBACT®: Powder for injectable preparation I.V. way (Infusion).

- Box of 1 Vial of TAZOBACT® 2 g / 250 mg.
- Box of 1 Vial of TAZOBACT® 4 g / 500 mg.

COMPOSITION :

- ***For one Vial of TAZOBACT® 2 g / 250 mg:***

Piperacillin ..... 2.0 g
(under sodium form) ..... 2.085 g
Tazobactam ..... 250 mg
(under sodium form) ..... 268.3 mg

- ***For one vial of TAZOBACT® 4 g / 500 mg:***

Piperacillin ..... 4.0 g
(under sodium form) ..... 4.170 g
Tazobactam ..... 500 mg
(under sodium form) ..... 536.6 mg

Content of sodium: 108 mg / Vial of TAZOBACT® 2g / 250mg and 216mg/ Vial of TAZOBACT® 4g /500mg

PHARMACO-THERAPEUTICAL CLASS:
The piperacillin is an antibiotic of beta-lactam family of penicillins group.
The tazobactam is an inhibitor of betalactamases.

INDICATIONS :
They are limited to infections caused by germs defined as sensitive in particular in their manifestations:

- Low respiratory.
- Urinary to the exclusion of prostaties.
- Intra-abdominals and biliary.
- Cutaneous.
- Feverish episodes for the neutropenic patients.

CONTRA-INDICATIONS:
Allergy to beta-lactams (including penicillins and cephalosporins) or inhibitors of betalactamases.

WARNINGS AND PRECAUTIONS OF USE

Warnings:
The emergence of any allergic reaction imposes the treatment's stop.
Before being treated by this medicament, alert your doctor if you had, while being treated by a previous antibiotic (even with another antibiotic family) an allergic reaction.
Some pseudomembranous colitis (intestine disease with diarrhoea and abdominal pains caused by the antibiotics can take place during or after the antibacterial treatment.

Interactions with paraclinical tests:
As with other penicillins, the administration of TAZOBACT® may result in a false-positive reaction for glucose in the urine using a copper-reduction method. It is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.
Crossed reactions with Platelia aspergillus EIA test:
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. Cross-reactions with non-*Aspergillus* polysaccharides and polyfuranoses with Bio-Rad Laboratories Platelia *Aspergillus* EIA test have been reported. Therefore, positive test results in patients receiving piperacillin-tazobactam should be interpreted cautiously and confirmed by other diagnostic methods.

Precautions of use:
Use this medicament with precaution in the cases of:

- Renal failure or haemodialysis
- Virus infections of herpes virus group.
- Infectious mononucleosis.
- Hyponatraemic diet.
- Hypokalemia.

This medicament contains sodium. This medicament contains 108 mg / Vial of TAZOBACT® 2g / 250mg and 216mg/ Vial of TAZOBACT® 4g /500mg. Take in to account patients controlling their food provision of sodium.

MEDICAMENTS INTRACTIONS AND OTHER INTERACTIONS:
This medicament is generally UNADVISABLE in association with the methodrexate (anti-cancerous medicament).
YOU SHOULD SIGNAL ANY OTHER CONCOMITANT TREATMENT TO YOUR DOCTOR.

PREGNANCY AND LACTATION:

Pregnancy:
This medicament can be used during pregnancy only if necessary.

Lactation:
This medicament is excreted in the mother's milk, yet, lactation is possible. However, in case of digestive troubles for the infant (diarrhea, candidiasis), or rash, lactation must be interrupted or suspended until the end of treatment.

SIDE EFFECTS:

- Blood and lymphatic system:

Very rare: anaemia, haemolytic anaemia, coombs direct test positive, bleeding (including purpura epistaxis, the bleeding time prolonged), prolonged partial thromboplastine time, prothrombine time prolonged, eosinophilia, leucopenia, neutropenia, thrombocytopenia, pancytopenia, agranulocytosis, trombocytosis.

- The immune system disorders

Very rare: hypersensitivity, anaphylactoid reactions.

- Metabolism and nutritional disorders:

Very rare: hypokalemia.

- Neurological disorders:

Rare: hallucination.
Hepatobiliary disorders:
Very rare: increase of transaminase, increase of bilirubin, increase of alkaline phosphatises.

- Vascular disorders: hypotension.
- Gastro-intestinal disorders:

Frequent: diarrhea, nausea, vomiting.
Rare: constipation, stomatitis, dry mouth.
Very rare: pseudomembranous colitis.

- Cutaneous and sub-cutaneous disorders:

Frequent: rash, erythema, enough numerous cutaneous reactions from allergic type (3.1 % upon 1200 patients), pruritus, urticaria.
Rare: polymorph erythema, cutaneous rash, maculopapular rash, exanthem, eczema.
Very rare: Stevens-Jonhson syndrome, Lyell syndrome, bullous dermatitis.

- Disorders of connective tissue, bone and musculoskeletal disorders: arthralgia, muscular weakness, myalgia.
- Renal and urinary disorders:

Less frequent: increase of creatininemia.
Very rare: interstitial nephritis, renal failure, increase of uraemia.

- General disorders:

Rare: fever, asthenia.
The treatment by piperacillin has been associated with an increase of fever and rash incidences in patients suffering from cysticfibrosis.
The administration of high posologies of beta-lactams, particularly for those suffering from renal failure, can lead to encephalophathies (consciousness troubles, abnormal movements, convulsive crises).
SIGNAL TO YOUR DOCTOR OR PHARMACIST ANY UNDESIRABLE EFFECT WHICH HASN'T BEEN MENTIONED IN THIS INSERT.

POSOLOGY AND METHOD OF ADMINISTRATION:

Posology:

Adult:
The usual posology is 4 g/500 mg (piperacillin/tazobactam) every 8 hours: 12 g/1.5 g a day.
The posology depends on the infections severity and localization, as well as the patient's weight; it can be increased until 4g / 500 mg every 6 hours, so be it 16 g / 2g a day.

More than 12 years-old children:
The posology is from 240 mg/30 mg to 320 mg/40 mg by kg a day of piperacillin and tazobactam, divided upon 3 to 4 infusions.

Renal failure, haemodialysed patient and old subjects:
The dose will be adapted.

Creatinine clearance ml/min	The maximum daily recommended dose
> 40	No adjustment
20 - 40	12g (piperacillin) – 1.5g (tazobactam) divided upon 3 injections (4 g/500 mg × 8 hours)
< 20 and haemadialysis	8g (piperacillin) – 1g (tazobactam) divided upon 2 injections (4 g/500 mg × 12 hours)

For haemodialysed patients, the daily posology is 8 g / 1 g, divided upon two administrations at 12 hours interval. After each haemodialysis session, an additional dose of 2 g / 250 mg will be adapted.
For old subjects whose creatinine clearance is superior to 40 ml / min, there is no posological modification; if it is inferior to 40 ml /min, the adaptation will be the same for those suffering from renal failure.

Administration method:
Intravenous infusion.
The reconstituted solution will be used during an infusion of 30 minutes.
Reconstituted solutions would be used immediately.

PARTICULAR STORAGE CONDITIONS:

- Before reconstitution: keep the medicament at temperature lower than 25°C.
- After reconstitution: solution would be used immediately.

LIST I
M.A. TAZOBACT® 2 g/ 250 mg : 909 393 3H
M.A. TAZOBACT® 4 g/ 500 mg : 909 393 4H

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 the pharmacist are the 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 of children.

COUNCIL OF ARAB HEALTH MINISTERS

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