For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Piperacillin (4 g) and Tazobactam (0.5 g) For Injection USP

BRODACTAM™ 4.5gm

COMPOSITION: Each vial contains Sterile Piperacillin Sodium USP equivalent to Piperacillin….4.0 g Tazobactam Sodium equivalent to Tazobactam…..…0.5 g.

Sodium content: 216 mg per vial (9.39mEq)

THERAPEUTIC INDICATION: BRODACTAM™, is indicated for treatment of the following systemic and/or local bacterial infections caused by gram positive or gram negative aerobic or anaerobic organisms susceptible to piperacillin/tazobactam or piperacillin:- Adults: Lower respiratory tract infections, Urinary tract infections, Intra-abdominal infections, Skin and skin structure infections, Bacterial septicaemia, Polymicrobial Infections (gram-positive/gram-negative aerobes and anaerobes). Children: Intra-abdominal infections including appendicitis complicated by rupture with peritonitis or abscess formation and biliary infections in hospitalized children aged 212 years. Bacterial infections in neutropenic children in combination with an aminoglycoside.In serious infections, empiric therapy may be initiated with pipercillin/tazobactam prior to the availability of the results of sensitivity tests.

DOSAGE & ADMINISTRATION: Administration is by slow intravenous injection (over at least 3-5 minutes) or by slow intravenous infusion (over 20-30 minutes). *Adults and children over 12 years with normal renal function :* In general, the recommended total daily dosage is 12 g piperacillin/1.5 g tazobactam given in divided doses every 6 or 8 hours. *Children aged 2-12 years:* Infections:

Dose per weight and treatment frequency	**Indication / condition**
80 mg Piperacillin / 10 mg Tazobactam per kg body weight / every 6 hours	Neutropenic children with fever suspected to be due to bacterial infections*
100 mg Piperacillin / 12.5 mg Tazobactam per kg body weight / every 8 hours	Complicated intra-abdominal infections*

*Not to exceed the maximum 4 g / 0.5 g per dose over 30 minutes.

Children under 2 years: The safety and efficacy of piperacillin/tazobactam in children 0 - 2 years of age has not been established. *Elderly:* No dose adjustment is required for the elderly with normal renal function or creatinine clearance values above 40 ml/min.

Renal Impairment:The intravenous dose should be adjusted to the degree of actual renal impairment as follows

Creatinine clearance (ml/min)	**Recommended piperacillin/tazobactam dosage**
> 50	No adjustment
≤ 50	70 mg piperacillin / 8.75 mg tazobactam / kg every 8 hours.

Hepatic Impairment: No dose adjustment is necessary

SAFETY RELATED INFORMATION:

Contraindications: Hypersensitivity to the active substances, any other penicillin-antibacterial agent or to any of the excipients. History of acute severe allergic reaction to other beta-lactam active substances.

Pregnancy: Piperacillin/ tazobactam should only be used during pregnancy if clearly indicated, i.e. only if the expected benefit outweighs the possible risks to the pregnant woman and foetus. Piperacillin and tazobactam cross the placenta.

Lactation: Women who are breast-feeding should be treated only if the expected benefit outweighs the possible risks to the nursing woman and child. Piperacillin is excreted in low concentrations in human milk**.**

Special Warnings and Special Precautions for use: The selection of piperacillin/ tazobactam to treat an individual patient should take into account the appropriateness of using a broad-spectrum semi-synthetic penicillin based on factors such as the severity of the infection and the prevalence of resistance to other suitable antibacterial agents. Careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, other beta-lactam agents and other allergens. Serious and occasionally fatal

hypersensitivity (anaphylactic/anaphylactoid [including shock]) reactions have been reported in patients receiving therapy with penicillins including piperacillin sodium-tazobactam sodium combination. Antibiotic-induced pseudomembranous colitis may be manifested by severe, persistent diarrhoea which may be life-threatening. In these cases piperacillin/ tazobactam, should be discontinued. Therapy with piperacillin/ tazobactam may result in the emergence of resistant organisms, which might cause super-infections. Leukopenia and neutropenia may occur, especially during prolonged therapy. Bleeding manifestations have occurred in some patients receiving β-lactam antibiotics. As with other penicillins, neurological complications in the form of convulsions may occur when higher doses are administered, especially in patients with impaired renal function. Hypokalaemia may occur in patients with low potassium reserves or those receiving concomitant medications that may lower potassium levels. Controlled sodium diet should be taken into consideration.

ADVERSE REACTIONS: Diarrhoea, Nausea, Vomiting, Rash, Maculopapular rash, Hypokalemia, Bronchospasm

For full prescribing information please contact: Sanofi India Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

Source:

- *ZOB/PI/IN/2013/02 dated 27 August 2013{GSK's Zobactin's prescribing information)*
- *Potential Signal & recommendation for label change for FDC of Piperacillin/Tazobactam dated 23rd December 2015*

Updated: May 2016