

STERIMAX

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January 16, 2017

Temporary Importation of Canadian Piperacillin and Tazobactam for Injection to Address Drug Shortage

Dear Healthcare Professional:

Due to the current critical shortage of Piperacillin and Tazobactam for Injection products in the United States (U.S.) market, SteriMax Inc. (SteriMax) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of the drug. SteriMax has initiated temporary importation of non-FDA approved Piperacillin and Tazobactam for Injection (3.375 g/vial, 4.5 g/vial, and 40.5 g/vial) into the U.S. market. The Piperacillin and Tazobactam for Injection from SteriMax is marketed in Canada and is manufactured at an FDA-inspected facility that is in compliance with current good manufacturing practice requirements.

X-Gen Pharmaceuticals will distribute SteriMax's Piperacillin and Tazobactam for Injection to address the critical shortage. At this time, no other entity except SteriMax or its distributor X-Gen Pharmaceuticals is authorized by the FDA to import or distribute SteriMax's Piperacillin and Tazobactam for Injection in the United States.

Effective immediately, X-Gen Pharmaceuticals will distribute the following presentations of SteriMax's Piperacillin and Tazobactam for Injection:

SteriMax Piperacillin and Tazobactam for Injection	
3.375 g/vial (equivalent to 3 g of piperacillin and 0.375 g of tazobactam)	DIN: 02362627 (Canada)
4.5 g/vial (equivalent to 4 g of piperacillin and 0.5 g of tazobactam)	DIN: 02362635 (Canada)
40.5 g/vial (equivalent to 36 g of piperacillin and 4.5 g of tazobactam)	DIN: 02439131 (Canada)

Note: DIN refers to Drug Identification Number for products marketed in Canada.

The barcode may not register accurately on the U.S. scanning systems. The barcode used for SteriMax's non-U.S. approved Piperacillin and Tazobactam for Injection is an international pharmaceutical manufacturing code and may not be appropriately recognized by scanning systems used in the U.S. Institutions should confirm the barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

The vial and carton labels will display the text used and approved for marketing the products in Canada with both English and French translations. At the end of this letter, you will find a product comparison table and a comparison of the carton and vial labels with the U.S. FDA reference listed drug (RLD).

It is important to note that there are differences in the format and content of the labeling between the RLD and SteriMax's Piperacillin and Tazobactam for Injection. In particular, for the U.S. market, we would like to highlight the following instructions:

- **Please reconstitute the SteriMax product with only the following Compatible Reconstitution Diluents:** 0.9% Sodium Chloride Injection, Sterile Water for Injection, Dextrose 5% Injection.
- **Please dilute the reconstituted product with the following Compatible Intravenous Solutions:** 0.9% Sodium Chloride Injection, Sterile Water for Injection, 5% Dextrose Injection, 6% Dextran in Saline.

We also recommend the following for the use of SteriMax's Piperacillin and Tazobactam for Injection as temporary supply in the U.S.:

- Store original vials at controlled room temperature (20-25°C [68°F to 77°F]) prior to reconstitution.
- Due to unique regulatory requirements in the U.S., this formulation of Piperacillin and Tazobactam for Injection is considered NOT compatible with Lactated Ringer's Solution (LRS), so LRS should not be used as a diluent.
- Please discard unused portions of reconstituted as well as further diluted product including product stored in I.V. bags after storage for 24 hours at room temperature (20°C to 25°C [68°F to 77°F]), or 48 hours when refrigerated (2°C to 8°C [36°F to 46°F]).
- Single dose or pharmacy vials should not be frozen after reconstitution.

Please note that SteriMax Piperacillin and Tazobactam for Injection and aminoglycosides are recommended for separate administration. SteriMax Piperacillin and Tazobactam for Injection is not compatible with Tobramycin for simultaneous co-administration via Y-site infusion. Compatibility of SteriMax Piperacillin and Tazobactam for Injection with other aminoglycosides has not been established.

Piperacillin and Tazobactam for Injection is available only by prescription in the U.S.

Finally, please ensure that your staff and others in your institution who may be involved in the administration of Piperacillin and Tazobactam receive a copy of this letter and review the information.

If you have any questions about the information contained in this letter or the use of SteriMax's Piperacillin and Tazobactam for Injection, please contact SteriMax Quality Assurance or Regulatory Affairs at 1-800-881-3550 (Monday – Friday, 9AM to 5PM, Eastern Standard Time).

To place an order, please contact X-Gen Pharmaceuticals Customer Service/Order Entry at 1-866-390-4411 (Monday – Friday, 9AM to 5PM, Eastern Standard Time).

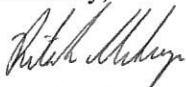
We encourage healthcare providers to report any adverse events and medication errors that occur while using this product, as for any other drug. To report adverse events or quality problems associated with the use of this product, please call SteriMax Quality Assurance at 1-800-881-3550.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

We remain at your disposal to answer any questions you may have about our product; and provide more information if needed.

Sincerely,



Ritesh Acharya,

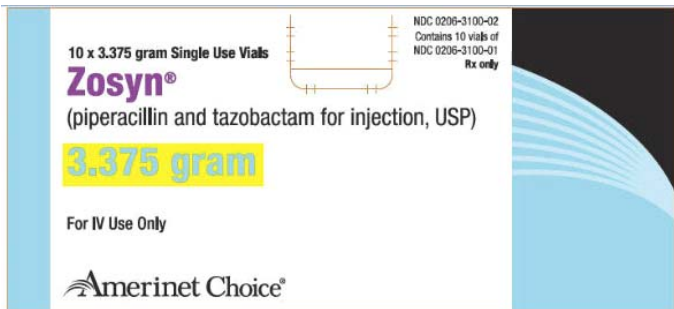
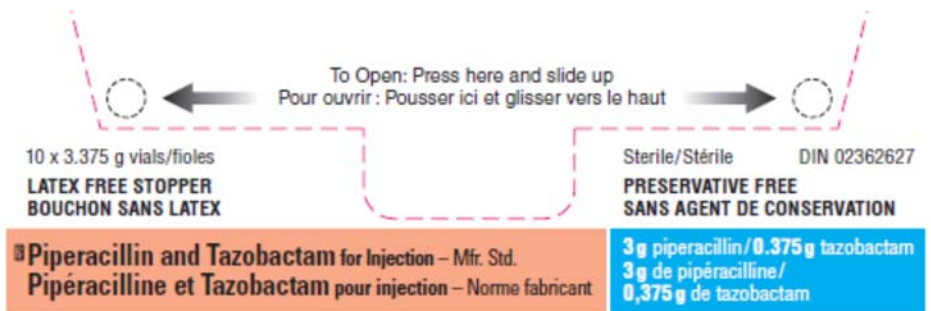
Director of Medical Affairs

SteriMax Inc.

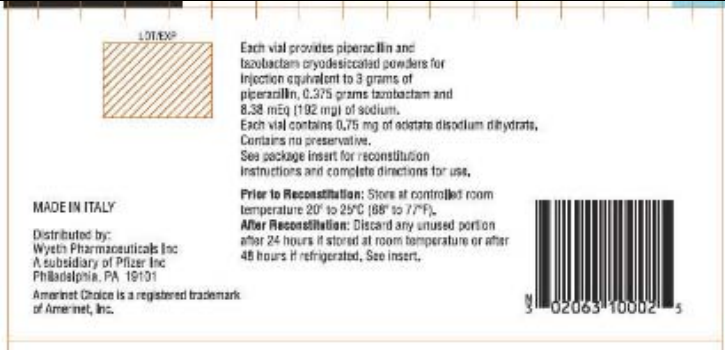
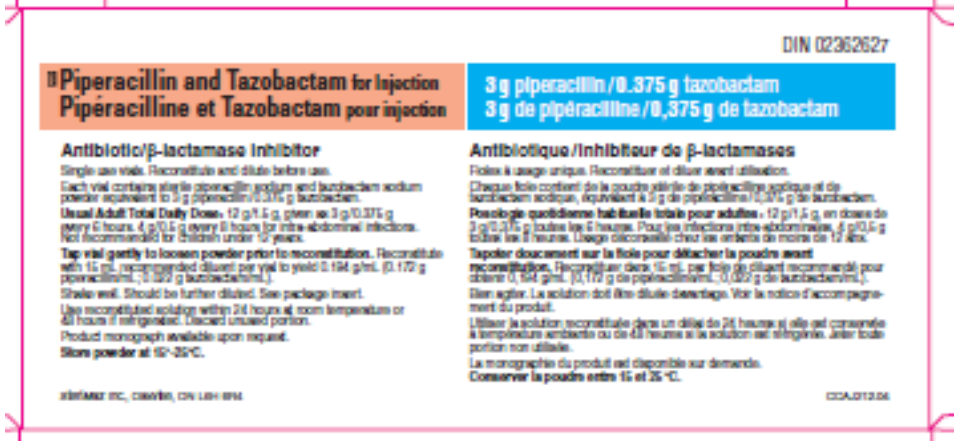
Product Comparison Table

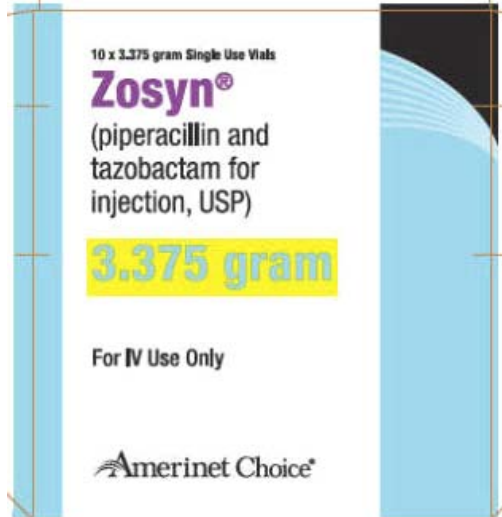
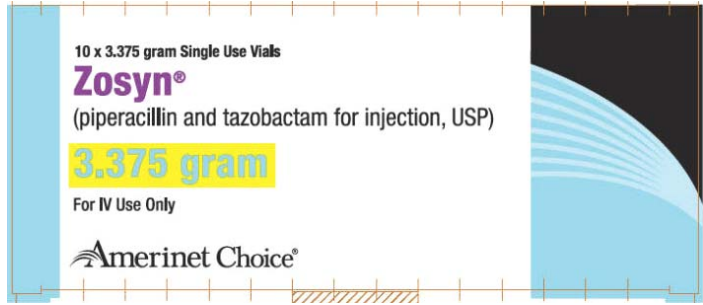
	SteriMax Piperacillin and Tazobactam for Injection	Zosyn®
Composition	Each gram of piperacillin contains 2.36 mEq (54.28 mg) of Na ⁺ (sodium)	Each gram of piperacillin contains 2.84 mEq (65 mg) of Na ⁺ (sodium)
3.375 g/vial	Each vial: piperacillin sodium equivalent to 3 grams of piperacillin and tazobactam sodium equivalent to 0.375 gram of tazobactam.	Each vial: piperacillin sodium equivalent to 3 grams of piperacillin and tazobactam sodium equivalent to 0.375 gram of tazobactam. 0.75 mg of EDTA.
4.5 g/vial	Each vial: piperacillin sodium equivalent to 4 grams of piperacillin and tazobactam sodium equivalent to 0.5 gram of tazobactam.	Each vial: piperacillin sodium equivalent to 4 grams of piperacillin and tazobactam sodium equivalent to 0.5 gram of tazobactam. 1 mg of EDTA.
13.5 g/vial	Each vial: piperacillin sodium equivalent to 12 grams of piperacillin and tazobactam sodium equivalent to 1.5 gram of tazobactam.	N/A
40.5 g/vial	Each vial: piperacillin sodium equivalent to 36 grams of piperacillin and tazobactam sodium equivalent to 4.5 grams of tazobactam.	Each vial: piperacillin sodium equivalent to 36 grams of piperacillin and tazobactam sodium equivalent to 4.5 grams of tazobactam.
Active Ingredient	Piperacillin and tazobactam	Piperacillin and tazobactam
Strength	3.375 g/vial, 4.5 g/vial, 13.5 g/vial, 40.5 g/vial	3.375 g/vial, 4.5 g/vial, 13.5 g/vial, 40.5 g/vial
Inactive Ingredients	N/A	3.375 g/vial: 0.75 mg EDTA 4.5 g/vial: 1 mg EDTA
Physiochemical Parameters	White to off white sterile powder Highly water soluble	Information not available.
pH	5.0 – 7.0	Information not available.
Description	White to off-white sterile powder	White to off-white sterile powder
How Supplied	3.375 g/vial: single dose glass vial 4.5 g/vial: single dose glass vial 13.5 g/vial: pharmacy bulk glass vial 40.5 g/vial: pharmacy bulk glass vial	3.375 g/vial: single dose glass vials 4.5 g/vial: single dose glass vial -- 40.5 g/vial: pharmacy bulk glass vial
Country-Specific Information	Canada: Drug Identification Numbers (DINs) 3.375 g/vial: DIN 02362627	

	4.5 g/vial: DIN 02362635 13.5 g/vial: DIN 02377748 40.5 g/vial: DIN 02439131
	USA: Special Import Permit issued by FDA
Drug Status	Prescription
Authorization Holder	SteriMax Inc. 2770 Portland Drive Oakville, ON L6H 6R4

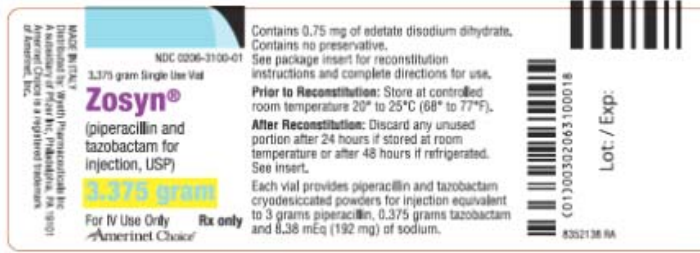
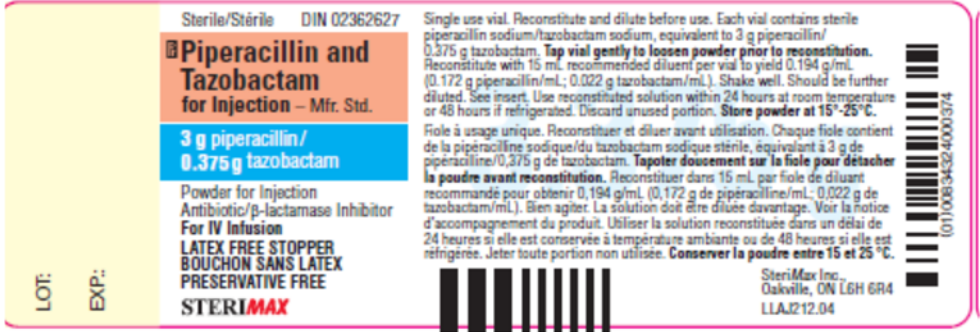
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Strength		3.375 g/vial
Carton Label – Principal Display	<p><u>Principal Display Panel</u> NDC 0206-3100-02 Contains 10 vials of NDC 0206-3100-01 Rx only</p> <p>10 x 3.375 gram Single Use Vials Zosyn® (piperacillin and tazobactam for injection, USP) 3.375 gram For IV Use Only Amerinet Choice®</p> 	<p><u>Principal Display Panel</u> 10 x 3.375 g vials/fioles LATEX FREE STOPPER/BOUCHON SANSLATEX DIN 02362627 Sterile/Stérile</p> <p>PRESERVATIVE FREE / SANS AGENT DE CONSERVATION</p> <p>PrPiperacillin and Tazobactam for Injection – Mfr. Std. Pipéracilline et Tazobactam pour inection – Norme fabricant 3g piperacillin/0.375 g tazobactam 3 g de pipéracilline/0.375 g tazobactam</p> <p>Sterile piperacillin sodium / tazobactam sodium lyophilized powder for injection Poudre stérile lyophilisée pour injection de pipéracilline sodique / de tazobactam sodique</p> <p>For intravenous infusion / Pour perfusion intraveineuse Antibiotic/β-lactamase inhibitor - Antibiotique/Inhibiteur de β-lactamase Sterile/Stérile</p> <p>PRESERVATIVE FREE / SANS AGENT DE CONSERVATION</p> <p>STERIMAX</p>  <p>10 x 3.375 g vials/fioles LATEX FREE STOPPER BOUCHON SANS LATEX</p> <p>Sterile/Stérile DIN 02362627 PRESERVATIVE FREE SANS AGENT DE CONSERVATION</p> <p>PrPiperacillin and Tazobactam for Injection – Mfr. Std. Pipéracilline et Tazobactam pour injection – Norme fabricant</p> <p>3g piperacillin/0.375 g tazobactam 3g de pipéracilline/0.375 g de tazobactam</p> <p>Sterile piperacillin sodium / tazobactam sodium lyophilized powder for injection Poudre stérile lyophilisée pour injection de pipéracilline sodique / de tazobactam sodique</p> <p>For intravenous infusion / Pour perfusion intraveineuse Antibiotic/β-lactamase Inhibitor • Antibiotique/inhibiteur de β-lactamases</p> <p>STERIMAX</p>

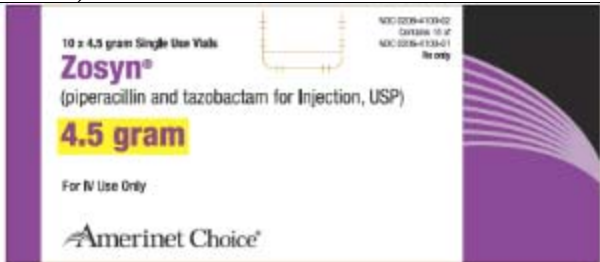
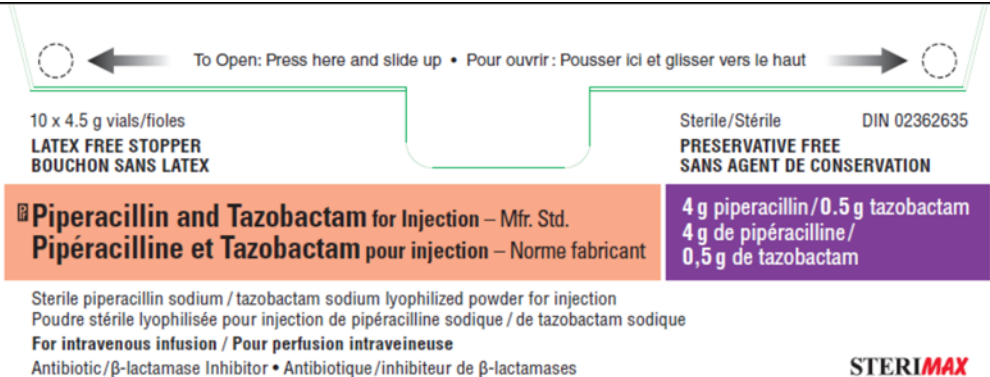
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr} Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Strength	3.375 g/vial	
Carton Label – Side Panel 1	<p>Side Panel 1 LOT/EXP</p> <p>Each vial provides piperacillin and tazobactam cryodesiccated powders for injection equivalent to 3 grams of piperacillin 0.375 grams tazobactam and 8.38 mEq (129 mg) of sodium. Each vial contains 0.75 mg of edetate disodium dihydrate. Contains no preservative. See package insert for reconstitution instructions and complete directions for use.</p> <p>Prior to Reconstitution: Store at controlled room temperature 20°C to 25°C (68°F to 77°F). After Reconstitution: Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See Insert. Barcode</p> <p>MADE IN ITALY</p> <p>Distributed by: Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101</p> <p>Amerinet Choice is a registered trademark Of Amerinet, Inc.</p>	<p>Side Panel 1</p> <p>DIN 02362627 ^{Pr}Piperacillin and Tazobactam for Injection Pipéracilline et Tazobactam pour injection 3 g piperacillin/0.375 g tazobactam 3 g de pipéracilline/0.375 g tazobactam</p> <p>Antibiotic / β-lactamase Inhibitor Single use vials. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 3 g piperacillin/0.375 g tazobactam Usual Adult Total Daily Dose: 12 g/1.5 g, given as 3 g/0.375 g every 6 hours. 4 g/0.5 g every 8 hours for intra-abdominal infections. Not recommended for children under 12 years. Tap vial gently to loose powder prior to reconstitution Reconstitute with 15 mL recommended diluent per vial to yield 0.194 g/mL (0.172 g piperacillin/mL; 0.022 g tazobactam/mL). Shake well. Should be further diluted. See package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Product monograph available upon request. Store powder at 15°-25°C.</p> <p>Antibiotique / inhibiteur de β-lactamases Fioles à usage unique. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalant à 3 g de pipéracilline / 0,375 g de tazobactam. Posologie quotidienne habituelle totale pour adultes : 12 g/1,5 g, en doses de 3 g/0,375 g toutes les 6 heures. Pour les infections intra-abdominales, 4 g/0,5 g toutes les 8 heures. Usage déconseillé chez les enfants de moins de 12 ans. Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 15 mL par fiole de diluant recommandé pour obtenir 0,194 g/mL (0,172 g de pipéracilline/mL; 0,022 g de tazobactam/mL). Bien agiter. La solution doit être diluée davantage. Voir la notice d'accompagnement du produit.</p>

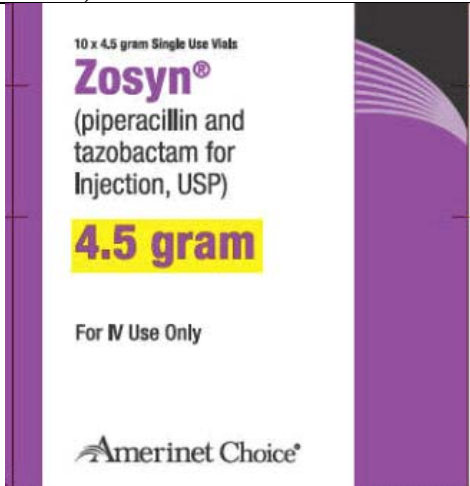
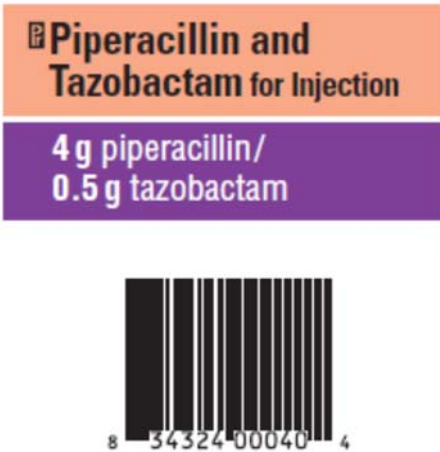
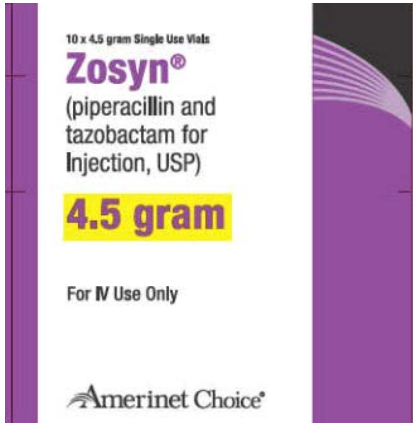
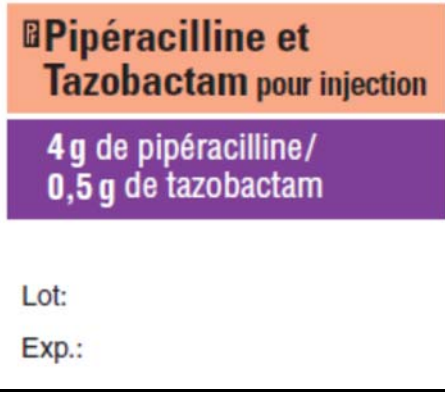
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>Each vial provides piperacillin and tazobactam cryodesiccated powders for injection equivalent to 3 grams of piperacillin, 0.375 grams tazobactam and 8.38 mEq (192 mg) of sodium. Each vial contains 0.75 mg of edetate disodium dihydrate. Contains no preservative. See package insert for reconstitution instructions and complete directions for use.</p> <p>Prior to Reconstitution: Store at controlled room temperature 20° to 25°C (68° to 77°F).</p> <p>After Reconstitution: Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See insert.</p> <p>MADE IN ITALY</p> <p>Distributed by: Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101</p> <p>Amerinet Choice is a registered trademark of Amerinet, Inc.</p> <p>3 02063 10002 5</p>	<p>Utiliser la solution reconstituée dans un délai de 24 heures si elle est conservée à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée. La monographie du produit est disponible sur demande.</p> <p>Conserver la poudre entre 15 et 25 °C.</p> <p>SteriMax Inc., Oakville, ON L6H 6R4</p>  <p>Piperacillin and Tazobactam for Injection Pipéracilline et Tazobactam pour injection</p> <p>3 g piperacillin / 0.375 g tazobactam 3 g de pipéracilline / 0,375 g de tazobactam</p> <p>Antibiotic/β-lactamase Inhibitor Single use vials. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 3 g piperacillin/0.375 g tazobactam. Usual Adult Total Daily Dose: 12 g/1.5 g, given as 3 g/0.375 g every 6 hours, 4 g/0.5 g every 8 hours for intra-abdominal infections. Not recommended for children under 12 years. Tap vial gently to loosen powder prior to reconstitution. Reconstitute with 15 mL recommended diluent per vial to yield 0.184 g/mL (0.172 g piperacillin, 0.022 g tazobactam). Shake well. Should be further diluted. See package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Product monograph available upon request. Store powder at 15°-25°C.</p> <p>Antibiotique/Inhibiteur de β-lactamases Fioles à usage unique. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalent à 3 g de pipéracilline/0,375 g de tazobactam. Possibilité quotidienne habituelle totale pour adultes : 12 g/1,5 g, en doses de 3 g/0,375 g toutes les 6 heures. Pour les infections intra-abdominales, 4 g/0,5 g toutes les 8 heures. Usage déconseillé chez les enfants de moins de 12 ans. Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer avec 15 mL, par fiole, du diluant recommandé pour obtenir 0,184 g/mL (0,172 g de pipéracilline, 0,022 g de tazobactam). Bien agiter. La solution doit être diluée davantage. Voir la notice d'accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conservée à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée. La monographie du produit est disponible sur demande. Conserver la poudre entre 15 et 25 °C.</p> <p>sterimax inc., oakville, on l6h 6r4</p> <p>CCA-2012-04</p>
Carton Label – Side Panel 2	Side Panel 2 10 x 3.375 gram Single Use Vials Zosyn® (piperacillin and tazobactam for injection, USP) 3.375 gram For IV Use Only Amerinet Choice®	Side Panel 2 PrPiperacillin and Tazobactam for Injection 3g piperacillin/0.375 g tazobactam Barcode

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
		
Carton Label – Side Panel 3	<p>Side Panel 3 10 x 3.375 gram Single Use Vials Zosyn® (piperacillin and tazobactam for injection, USP) 3.375 gram For IV Use Only Amerinet Choice®</p> 	<p>Side Panel 3 Pipéracilline et Tazobactam pour inction 3 g de pipéracilline/0.375 g tazobactam</p> <p>Lot: Exp.:</p>  <p>Lot: Exp.:</p>

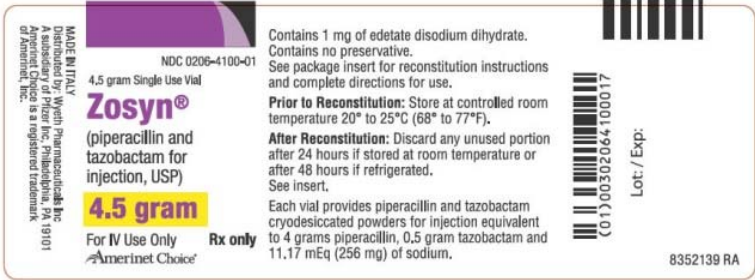
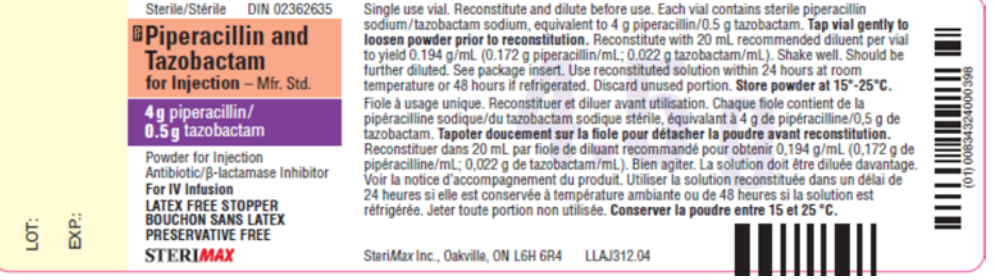
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Vial Label	<p>NDC 0206-3100-01 3.375 gram Single Use Vial Zosyn® (piperacillin and tazobactam for injection, USP) 3.375 gram For IV Use Only Rx only Amerinet Choice®</p> <p>Contains 0.75 mg of edetate disodium dihydrate. Contains no preservative. See package insert for reconstitution instructions and complete directions for use. Prior to Reconstitution: Store at controlled room temperature 20°C to 25°C (68°F to 77°F). After Reconstitution: Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See Insert. Each vial provides piperacillin and tazobactam cryodesiccated powders Philadelphia, PA 19101 Amerinet Choice is a registered trademark Of Amerinet, Inc.</p>	<p>DIN 02362627 PrPiperacillin and Tazobactam for Injection – Mfr. Std. 3g piperacillin/0.375 g tazobactam Powder for Injection Antibiotic / β-lactamase Inhibitor For IV Infusion LATEX FREE STOPPER BOUCHON SANSLATEX PRESERVATIVE FREE SteriMax</p> <p>Single use vial. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 3 g piperacillin/0.375 g tazobactam Tap vial gently to loose powder prior to reconstitution. Reconstitute with 15 mL recommended diluent per vial to yield 0.194 g/mL (0.172 g piperacillin/mL; 0.022 g tazobactam/mL). Shake well. Should be further diluted. See insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Store powder at 15°-25°C.</p> <p>Fioles à usage unique. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalent à 3 g de pipéracilline / 0,375 g de tazobactam. Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 15 mL par fiole de diluant recommandé pour obtenir 0,194 g/mL (0,172 g de pipéracilline/mL; 0,022 g de tazobactam/mL). Bien agiter. La solution doit être diluée davantage. Voir la notice d'accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conserve à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée. Conserver la poudre entre 15 et 25 °C. Sterimax Inc., Oakville, ON L6H 6R4 Barcode Lot : EXP :</p>

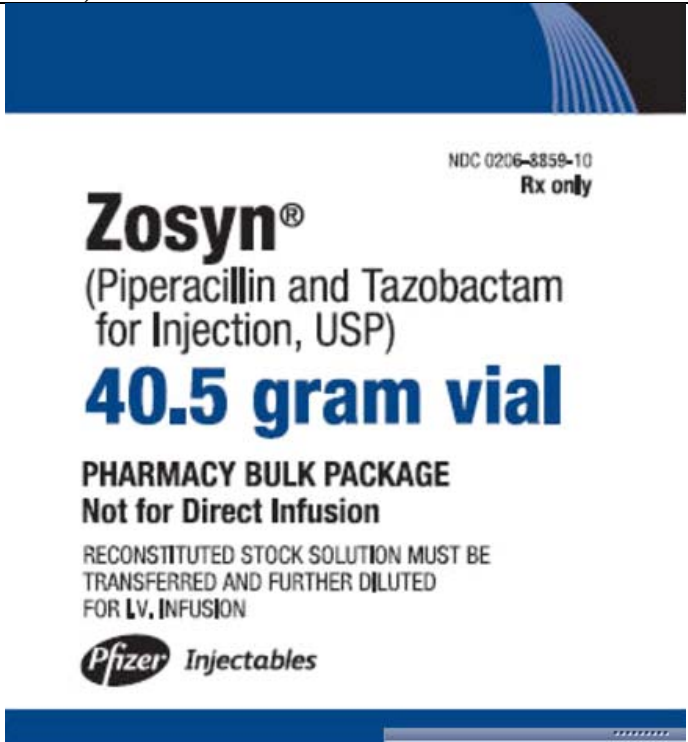
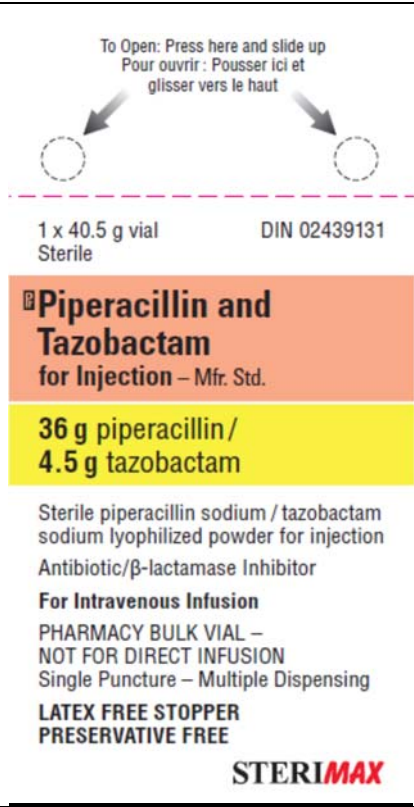
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr}Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
		
Strength		4.5 g/vial
Carton Label – Principal Display	<u>Principal Display</u> NDC 0206-4100-01 Contains 10 of NDC 0206-4100-01 Rx only 10 x 4.5 gram Single Use Vials Zosyn® (piperacillin and tazobactam for injection, USP) 4.5 gram For IV Use Only Amerinet Choice®	<u>Principal Display Panel</u> 10 x 4.5 g vials/foies LATEX FREE STOPPER/BOUCHON SAN SLATEX DIN 02362635 ^{Pr} Piperacillin and Tazobactam for Injection – Mfr. Std. Pipéracilline et Tazobactam pour inection – Norme fabricant 4 g piperacillin/0. 5 g tazobactam 4 g de pipéracilline/0.5 g tazobactam Sterile piperacillin sodium / tazobactam sodium lyophilized powder for injection Poudre stérile lyophilisée pour injection de pipéracilline sodique / de tazobactam sodique For intravenous infusion / Pour perfusion intraveineuse Antibiotic/β-lactamase inhibitor Antibiotique/Inhibiteur de β-lactamase Sterile/Stérile PRESERVATIVE FREE / SANS AGENT DE CONSERVATION STERIMAX


Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr}Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>The image shows the Zosyn carton and a vial. The carton is white with purple and yellow accents. It displays '10 x 4.5 gram Single Use Vials', 'Zosyn® (piperacillin and tazobactam for Injection, USP)', '4.5 gram', 'For IV Use Only', and the 'Amerinet Choice' logo. The vial is purple with a white label showing the same product information.</p>	 <p>The image shows the proposed SteriMax carton and vial. The carton is white with orange and purple accents. It displays '10 x 4.5 g vials/foies', 'LATEX FREE STOPPER BOUCHON SANS LATEX', 'Sterile/Stérile', 'PRESERVATIVE FREE SANS AGENT DE CONSERVATION', 'DIN 02362635', and the product name in English and French. The vial is purple with a white label showing the same product information. The SteriMax logo is at the bottom right.</p>
Carton Label – Side Panel 1	<p><u>Side Panel 1</u> LOT/EXP</p> <p>Each vial provides piperacillin and tazobactam cryodesiccated powders for injection equivalent to 4 grams of piperacillin, 0.5 grams tazobactam and 11.17 mEq (265 mg) of sodium. Each vial contains 1 mg of edetate disodium dihydrate. Contains no preservative. See package insert for reconstitution instructions and complete directions for use.</p> <p>Prior to Reconstitution: Store at controlled room temperature 20°C to 25°C (68°F to 77°F). After Reconstitution: Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See Insert. Barcode</p> <p>MADE IN ITALY</p> <p>Distributed by: Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101</p> <p>Amerinet Choice is a registered trademark</p>	<p><u>Side Panel 1</u> DIN 02362635</p> <p>^{Pr}Piperacillin and Tazobactam for Injection Pipéracilline et Tazobactam pour inection 4 g piperacillin/0.5 g tazobactam 4 g de pipéracilline/ 0. 5 g tazobactam</p> <p>Antibiotic / β-lactamase Inhibitor Single use vials. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 4 g piperacillin/0. 5 g tazobactam Usual Adult Total Daily Dose: 12 g/1.5 g, given as 3 g/0.375 g every 6 hours. 4 g/0.5 g every 8 hours for intra-abdominal infections. Not recommended for children under 12 years. Tap vial gently to loose powder prior to reconstitution Reconstitute with 20 mL recommended diluent per vial to yield 0.194 g/mL (0.172 g piperacillin/mL; 0.022 g tazobactam/mL). Shake well. Should be further diluted. See package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Product monograph available upon request. Store powder at 15°-25°C. Sterimax Inc., Oakville, ON L6H 6R4</p>

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr}Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
		
Carton Label – Side Panel 3	<u>Side Panel 3</u> 10 x 4.5 gram Single Use Vials Zosyn® (piperacillin and tazobactam for injection, USP) 4.5 gram For IV Use Only Amerinet Choice® 	<u>Side Panel 3</u> Pipéracilline et Tazobactam pour inection 3 g de pipéracilline/0.375 g tazobactam Lot: Exp.: 

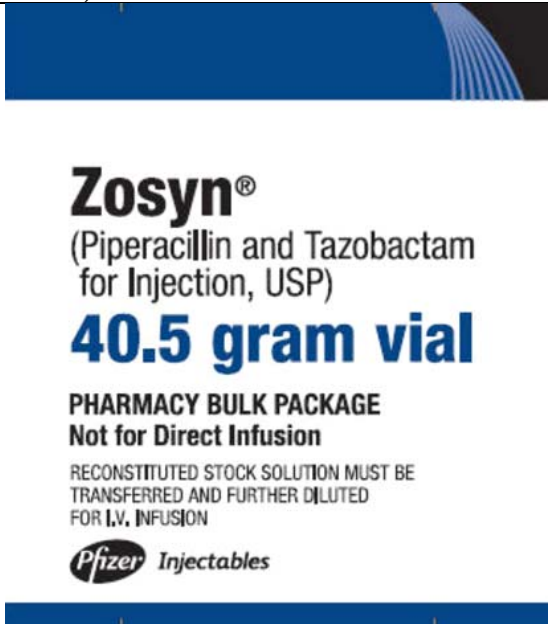
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Vial Label	<p>NDC 0206-4100-01 4.5 gram Single Use Vial Zosyn® (piperacillin and tazobactam for injection, USP) 4.5 gram For IV Use Only Rx only Amerinet Choice®</p> <p>Contains 1 mg of edetate disodium dihydrate. Contains no preservative. See package insert for reconstitution instructions and complete directions for use. Prior to Reconstitution: Store at controlled room temperature 20°C to 25°C (68°F to 77°F). After Reconstitution: Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See Insert. Each vial provides piperacillin and tazobactam cryodesiccated powders for injection equivalent to 4 grams of piperacillin 0.5 grams tazobactam and 11.17 mEq (256 mg) of sodium.</p> <p>Barcode Lot: / Exp:</p> <p>MADE IN ITALY Distributed by: Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101 Amerinet Choice is a registered trademark Of Amerinet, Inc.</p>	<p>DIN 02362635 PrPiperacillin and Tazobactam for Injection – Mfr. Std. 4 g piperacillin/0.5 g tazobactam Powder for Injection Antibiotic / β-lactamase Inhibitor For IV Infusion LATEX FREE STOPPER BOUCHON SANSLATEX PRESERVATIVE FREE SteriMax</p> <p>Single use vial. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 4 g piperacillin/0.5 g tazobactam Tap vial gently to loose powder prior to reconstitution. Reconstitute with 20 mL recommended diluent per vial to yield 0.194 g/mL (0.172 g piperacillin/mL; 0.022 g tazobactam/mL). Shake well. Should be further diluted. See insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Store powder at 15°-25°C.</p> <p>Fioles à usage unique. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalent à 4 g de pipéracilline / 0, 5 g de tazobactam. Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 20 mL par fiole de diluant recommandé pour obtenir 0,194 g/mL (0,172 g de pipéracilline/mL; 0,022 g de tazobactam/mL). Bien agiter. La solution doit être diluée davantage. Voir la notice d'accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conserve à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée. Conserver la poudre entre 15 et 25 °C. Sterimax Inc., Oakville, ON L6H 6R4 Barcode Lot : EXP. :</p>

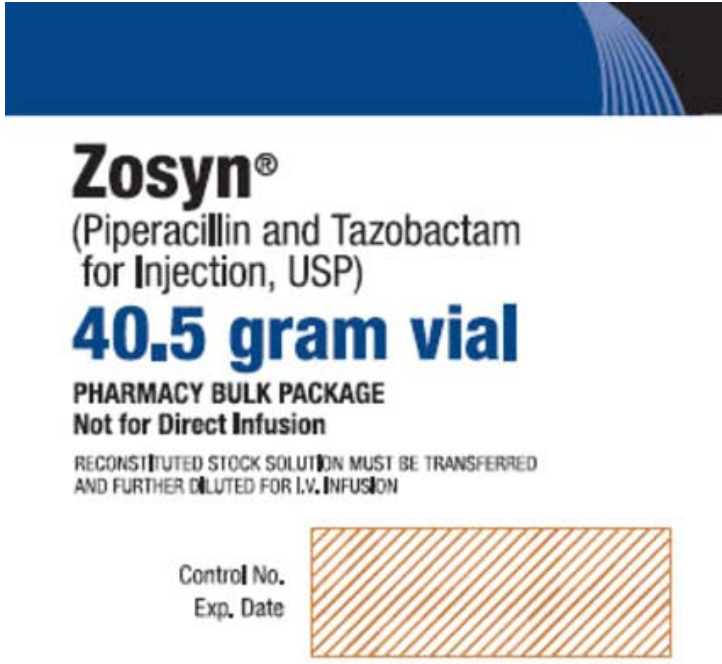
Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr}Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
		
Strength		40.5 g/vial
Carton Label – Principal Display Panel	<u>Principal Display Panel</u> NDC 0206-8859-10 Rx only Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial PHARMACY BULK PACKAGE Not for Direct Infusion RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION Pfizer Injectables	<u>Principal Display Panel</u> 1 x 4.5 g vial Sterile DIN 02439131 ^{Pr} Piperacillin and Tazobactam for Injection – Mfr. Std. 36 g piperacillin/4.5 g tazobactam Sterile piperacillin sodium / tazobactam sodium lyophilized powder for injection For intravenous infusion PHARMACY BULK VIAL – NOT FOR DIRECT INFUSION Single Puncture – Multiple Dispensing LATEX FREE STOPPER PRESERVATIVE FREE STERIMAX

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	^{Pr}Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>The image shows the front of a Zosyn vial label. At the top is a blue header with a white curved line. Below it, the text reads: 'NDC 0206-8859-10 Rx only', 'Zosyn® (Piperacillin and Tazobactam for Injection, USP)', '40.5 gram vial', 'PHARMACY BULK PACKAGE', 'Not for Direct Infusion', 'RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION', and the Pfizer Injectables logo at the bottom.</p>	 <p>The image shows a proposed vial label for SteriMax. It features a diagram of a vial with arrows indicating how to open it: 'To Open: Press here and slide up' and 'Pour ouvrir: Pousser ici et glisser vers le haut'. Below this, it says '1 x 40.5 g vial Sterile' and 'DIN 02439131'. The main label has an orange top section with 'Piperacillin and Tazobactam for Injection – Mfr. Std.', a yellow middle section with '36 g piperacillin / 4.5 g tazobactam', and a white bottom section with 'Sterile piperacillin sodium / tazobactam sodium lyophilized powder for injection', 'Antibiotic/β-lactamase Inhibitor', 'For Intravenous Infusion', 'PHARMACY BULK VIAL – NOT FOR DIRECT INFUSION', 'Single Puncture – Multiple Dispensing', 'LATEX FREE STOPPER', 'PRESERVATIVE FREE', and the 'STERIMAX' logo at the bottom.</p>
Carton Label – Side Panel 1	<u>Side Panel 1</u> Does not contain preservatives. Reconstitute with exactly 152 mL of a suitable diluent to achieve a concentration of 200 mg/mL of piperacillin and 25 mg/mL tazobactam. Discard any unused portion after 24 hours of stored at room temperature or after 48 hours if refrigerated. See package insert for complete directions for use. <u>Prior to Reconstitution:</u> Store at controlled room temperature 20° to 25°C (68° to 77°F).	<u>Side Panel 1</u> DIN 02439131 ^{Pr} Piperacillin and Tazobactam for Injection 36 g piperacillin/4.5 g tazobactam Antibiotic / β-lactamase Inhibitor For use in pharmacy (hospital) admixture program only. Single use vial. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 36 g piperacillin/4.5 g tazobactam. Usual Adult Total Daily Dose: 12 g/1.5 g, given as 3 g/0.375 g every 6 hours. 4 g/0.5 g every 8 hours for intra-abdominal infections. Not recommended for children under 12 years.

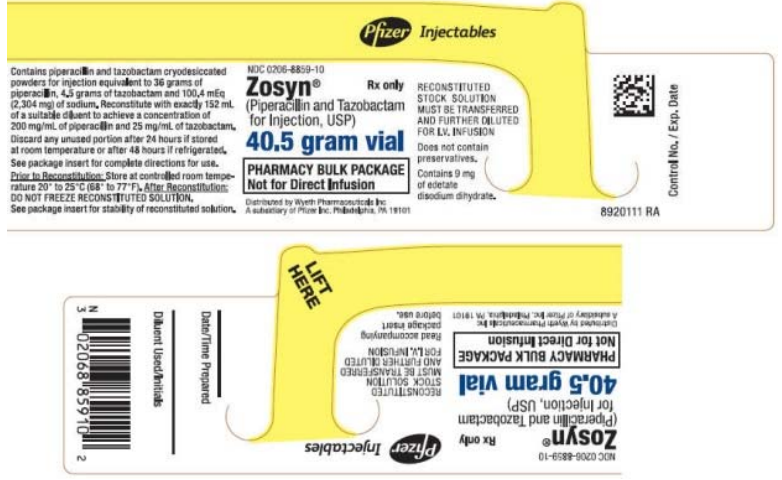

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	<p><u>After Reconstitution:</u> DO NOT FREEZE RECONSTITUTED SOLUTION. Se package insert for stability of reconstituted solution.</p> <p>Contains piperacillin and tazobactam cryodesiccated powders for injection equivalent to 36 grams of piperacillin and 4.5 grams of tazobactam and 100.4 mEq (2,304 mg) of sodium. Contains 9 mg of edetate disodium dihydrate.</p> <p>Distributed by: Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101</p> <p>Does not contain preservatives, Reconstitute with exactly 152 mL of a suitable diluent to achieve a concentration of 200 mg/mL of piperacillin and 25 mg/mL of tazobactam. Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated, See package insert for complete directions for use.</p> <p><u>Prior to Reconstitution:</u> Store at controlled room temperature 20° to 25°C (68° to 77°F).</p> <p><u>After Reconstitution:</u> DO NOT FREEZE RECONSTITUTED SOLUTION, See package insert for stability of reconstituted solution.</p> <p>Contains piperacillin and tazobactam cryodesiccated powders for injection equivalent to 36 grams of piperacillin, 4.5 grams of tazobactam and 100.4 mEq (2,304 mg) of sodium. Contains 9 mg of edetate disodium dihydrate,</p> <p>Distributed by Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc Philadelphia, PA 19101</p>	<p>Tap vial gently to loose powder prior to reconstitution Reconstitute with 152 mL recommended diluent per vial to yield 0.200 g/mL piperacillin and 0.025 g/ml tazobactam. Shake well. Should be further diluted - see package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Store powder at 15°-25°C. Product monograph available upon request.</p> <p>Sterimax Inc., Oakville, ON L6H 6R4</p>  <p>Antibiotic/β-lactamase Inhibitor</p> <p>For use in pharmacy (hospital) admixture program only. Single use vial. Reconstitute and dilute before use.</p> <p>Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 36 g piperacillin/4.5 g tazobactam.</p> <p>Usual Adult Total Daily Dose: 12 g/1.5 g, given as 3 g/0.375 g every 6 hours. 4 g/0.5 g every 8 hours for intra-abdominal infections. Not recommended for children under 12 years.</p> <p>Reconstitution: Tap vial gently to loosen powder prior to reconstitution. Reconstitute with 152 mL recommended diluent per vial to yield 0.200 g/mL piperacillin and 0.025 g/mL tazobactam. Shake well. Should be further diluted – see package insert.</p> <p>Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion.</p> <p>Store powder at 15°-25°C. Product monograph available upon request.</p> <p>SteriMax Inc., Oakville, ON L6H 6R4 CCAJ511.01</p>

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Carton Label – Side Panel 2	<p><u>Side Panel 2</u></p> <p>Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial PHARMACY BULK PACKAGE Not for Direct Infusion RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION Pfizer Injectables</p>	<p><u>Side Panel 2 (FRENCH)</u></p> <p>1 fiole de 40,5 g Stérile DIN 02439131</p> <p>Pipéracilline et Tazobactam pour inection – Norme fabricant 36 g de pipéracilline/4.5 g tazobactam Poudre stérile lyophilisée pour injection de pipéracilline sodique / de tazobactam sodique</p> <p>Antibiotique/Inhibiteur de β-lactamase</p> <p>Pour perfusion intraveineuse FIOLE GRAND FORMAT POUR PHARMACIES – NON DESTINÉE À L’INFUSION DIRECTE Ponction unique – doses multiples</p> <p>BOUCHON SANS LATEX SANS AGENT DE CONSERVATION</p> <p>STERIMAX</p>

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	P^rPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial</p> <p>PHARMACY BULK PACKAGE Not for Direct Infusion</p> <p>RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION</p> <p>Pfizer <i>Injectables</i></p>	<p>1 fiole de 40,5 g DIN 02439131 Stérile</p> <p>Pipéracilline et Tazobactam pour injection – Norme fabricant</p> <p>36 g de pipéracilline/ 4,5 g de tazobactam</p> <p>Poudre stérile lyophilisée pour injection de pipéracilline sodique / de tazobactam sodique</p> <p>Antibiotique / inhibiteur de β-lactamases</p> <p>Pour perfusion intraveineuse FIOLE GRAND FORMAT POUR PHARMACIES – NON DESTINÉE À L'INFUSION DIRECTE Ponction unique – doses multiples</p> <p>BOUCHON SANS LATEX SANS AGENT DE CONSERVATION</p> <p>STERIMAX</p>
Carton Label – Side Panel 3	<u>Side Panel 3</u> Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial PHARMACY BULK PACKAGE Not for Direct Infusion RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION Control No. Exp. Date	<u>Side Panel 3 (FRENCH)</u> Antibiotique / inhibiteur de β-lactamases À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Fioles à usage unique. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalent à 36 g de pipéracilline / 4,5 g de tazobactam. Posologie quotidienne habituelle totale pour adultes : 12 g/1,5 g, en doses de 3 g/0,375 g toutes les 6 heures. Pour les infections intra-abdominales, 4 g/0,5 g toutes les 8 heures. Usage déconseillé chez les enfants de moins de 12 ans. Reconstitution: tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 152 mL par fiole de diluant recommandé pour obtenir 0,200 g/mL de pipéracilline et 0,025 g/mL de tazobactam.

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial PHARMACY BULK PACKAGE Not for Direct Infusion</p> <p>RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION</p> <p>Control No. Exp. Date</p>	<p>Bien agiter. La solution doit être diluée davantage. Voir la notice d’accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conservée à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée.</p> <p>Conserver la poudre entre 15 et 25 °C. La monographie du produit est disponible sur demande.</p> <p>SteriMax Inc., Oakville, ON L6H 6R4</p> <p>Antibiotique/inhibiteur de β-lactamase</p> <p>À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Fiole à usage unique. Reconstituer et diluer avant utilisation.</p> <p>Chaque fiole contient de la poudre stérile de piperacilline sodique et de tazobactam sodique, équivalant à 36 g de piperacilline/4,5 g de tazobactam.</p> <p>Posologie quotidienne habituelle totale pour adultes : 12 g/1,5 g, en doses de 3 g/0,375 g toutes les 6 heures. Pour les infections intra-abdominales, 4 g/0,5 g toutes les 8 heures. Usage déconseillé chez les enfants de moins de 12 ans.</p> <p>Reconstitution : Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 152 mL par fiole de diluant recommandé pour obtenir 0,200 g/mL de piperacilline et 0,025 g/mL de tazobactam.</p> <p>Bien agiter. La solution doit être diluée davantage. Voir la notice d’accompagnement du produit.</p> <p>Utiliser la solution reconstituée dans un délai de 24 heures si elle est conservée à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée.</p> <p>Conserver la poudre entre 15 et 25 °C. La monographie du produit est disponible sur demande.</p> <p>SteriMax Inc., Oakville, ON L6H 6R4</p>

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	P ^r Piperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
Vial Label	<p>Pfizer Injectables NDC 0206-8859-10 Zosyn® Rx only (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial PHARMACY BULK PACKAGE Not for Direct Infusion Distributed by Wyeth Pharmaceuticals Inc A subsidiary of Pfizer Inc, Philadelphia, PA 19101</p> <p>Contains piperacillin and tazobactam cryodesiccated powders for injection equivalent to 36 grams of piperacillin, 4.5 grams of tazobactam and 100.4 mEq (2,304 mg) of sodium. Reconstitute with exactly 152 mL of a suitable diluent to achieve concentration of 200 mg/mL of piperacillin and 25 mg/mL of tazobactam. Discard any unused portion after 24 hours if stored at room temperature or after 48 hours if refrigerated. See package insert for complete directions for use. <u>Prior to Reconstitution:</u> Store at controlled room temperature 20° to 25°C (68°C to 77°F). <u>After Reconstitution:</u> DO NOT FREEZE RECONSTITUTED SOLUTION. See package insert for stability of reconstituted solution.</p> <p>RECONSTITUTED STOCK SOLUTION MUST BE TRANSFERRED AND FURTHER DILUTED FOR I.V. INFUSION Does not contain preservatives. Contains 9 mg of edetate disodium dihydrate.</p> <p>Barcode 8920111 RA</p> <p>Control No./Exp. Date</p>	<p>DIN 02439131 P^rPiperacillin and Tazobactam for Injection – Mfr. Std. 36 g piperacillin/4.5 g tazobactam Powder for Injection Antibiotic / β-lactamase Inhibitor For Intravenous Infusion</p> <p>PHARMACY BULK VIAL – NOT FOR DIRECT INFUSION Single Puncture – Multiple Dispensing</p> <p>LATEX FREE STOPPER BOUCHON SANSLATEX PRESERVATIVE FREE SteriMax</p> <p>For use in pharmacy (hospital) admixture program only. Single use vial. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 36 g piperacillin/4.5 g tazobactam. Reconstitution: tap vial gently to loose powder prior to reconstitution. Reconstitute with 152 mL recommended diluent per vial to yield 0.200 g/mL of piperacillin and 0.025 g/mL of tazobactam. Shake well. Should be further diluted - see package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Store powder at 15°-25°C. Product monograph available upon request.</p> <p>À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Fioles à usage unique. Ponction unique – doses multiples. Reconstituer et diluer avant utilisation. Chaque fiole contient de la poudre stérile de pipéracilline sodique et de tazobactam sodique, équivalent à 36 g de pipéracilline / 4,5 g de tazobactam. Reconstitution: tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 152 mL par fiole de diluant recommandé pour obtenir 0,200 g/mL de pipéracilline et de 0,025 g/mL de tazobactam. Bien agiter. La solution doit être diluée davantage. Voir la notice d'accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conserve à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée.</p>

Item	Zosyn® (piperacillin and tazobactam for injection, USP) (Approved RLD Carton and Vial Label Information – Amerinet Choice)	PrPiperacillin and Tazobactam for Injection – Mfr. Std. (Proposed Carton and Vial Label Information – SteriMax Inc.)
	 <p>The image shows the label for a Zosyn 40.5 gram vial. The label is yellow and white. It features the Pfizer logo and the text 'Pfizer Injectables'. The main text reads: 'Zosyn® (Piperacillin and Tazobactam for Injection, USP) 40.5 gram vial'. Below this, it says 'PHARMACY BULK PACKAGE Not for Direct Infusion'. There is also a barcode and a QR code. The label includes detailed instructions for use, storage, and handling, as well as a warning to not freeze the reconstituted solution.</p>	<p>Conserver la poudre entre 15 et 25 °C. La monographie du produit est disponible sur demande.</p> <p>Barcode</p> <p>SteriMax Inc., Oakville, ON L6H 6R4 Lot : EXP. :</p> <div><div>Sterile/Stérile</div><div>DIN 02439131</div><div>Piperacillin and Tazobactam for Injection – Mfr. Std.</div><div>36 g piperacillin / 4.5 g tazobactam</div><div>Powder for Injection Antibiotic/β-lactamase Inhibitor For Intravenous Infusion PHARMACY BULK VIAL – NOT FOR DIRECT INFUSION Single Puncture – Multiple Dispensing LATEX FREE STOPPER BOUCHON SANS LATEX PRESERVATIVE FREE</div><div>STERIMAX</div></div> <p>For use in pharmacy (hospital) admixture program only. Single use vial. Reconstitute and dilute before use. Each vial contains sterile piperacillin sodium and tazobactam sodium powder equivalent to 36 g piperacillin/ 4.5 g tazobactam. Reconstitution: Tap vial gently to loosen powder prior to reconstitution. Reconstitute with 152 mL recommended diluent per vial to yield a concentration of 0.200 g/mL of piperacillin and 0.025 g/mL of tazobactam. Shake well. Should be further diluted – see package insert. Use reconstituted solution within 24 hours at room temperature or 48 hours if refrigerated. Discard unused portion. Store powder at 15°-25°C. Product monograph available upon request.</p> <p>À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Fiole à usage unique. Ponction unique – doses multiples. Reconstituer et diluer avant utilisation. Chaque fiole contient de la piperacilline sodique/du tazobactam sodique, équivalent à 36 g de piperacilline/4,5 g de tazobactam. Reconstitution : Tapoter doucement sur la fiole pour détacher la poudre avant reconstitution. Reconstituer dans 152 mL par fiole de diluant recommandé pour obtenir une concentration de 0,200 g/mL de piperacilline et de 0,025 g/mL de tazobactam. Bien agiter. La solution doit être diluée davantage – voir la notice d'accompagnement du produit. Utiliser la solution reconstituée dans un délai de 24 heures si elle est conservée à température ambiante ou de 48 heures si la solution est réfrigérée. Jeter toute portion non utilisée. Conserver la poudre entre 15 et 25 °C. La monographie du produit est disponible sur demande.</p> <div><div>Piperacillin and Tazobactam for Injection</div><div>40.5 g</div><div></div><div>SteriMax Inc., Oakville, ON L6H 6R4 LLAJ511.01</div></div> <p>(01)00834324001265</p> <p>Lot:</p>