

Astral SteriTech – Recalls all antibiotic injectable products

- On May 15, 2023, <u>Astral SteriTech announced</u> a user-level recall of all sterile antibiotic powders for injection because of quality concerns at its manufacturing facility. The sterility of these products cannot be assured.
- The recalled products were distributed by and labeled in the names of the following distributors: Civica, Inc., Meitheal Pharmaceuticals, Piramal Critical Care, or Xellia Pharmaceuticals.
 - Antibiotic injectable products made by other manufacturers are available for patients to use.

Product Description	Distributor Name on Label	Strength	NDC Number
Ampicillin sodium	Piramal Critical Care	250 mg	66794-0220-41
		500 mg	66794-0221-41
		1 g	66794-0222-41
		2 g	66794-0223-41
		10 g	66794-0224-15
	Xellia Pharmaceuticals	250 mg	70594-0084-02
		500 mg	70594-0085-02
		1 g	70594-0086-02
		2 g	70594-0087-02
		10 g	70594-0088-01
Ampicillin & sulbactam for injection	Civica, Inc.	1.5 g	72572-0021-10
		3 g	72572-0022-10
	Meitheal Pharmaceuticals	1.5 g	71288-0050-20
		3 g	71288-0060-30
		15 g	71288-0070-75
	Piramal Critical Care	1.5 g	66794-0206-41; 66794-0241-41
		3 g	66794-0207-41; 66794-0242-41
		15 g	66794-0208-15; 66794-0243-15
	Xellia Pharmaceuticals	1.5 g	70594-0081-02
		3 g	70594-0082-02
		15 g	70594-0083-01
Cefepime for injection (mixture of Cefepime HCI and L-arginine)	Civica, Inc.	1 g	72572-0057-10
		2 g	72572-0058-10
	Meitheal Pharmaceuticals	2 g	71288-0090-20
		1 g	66794-0209-41

	Piramal Critical Care	2 g	66794-0210-41
X	Xellia Pharmaceuticals	1 g	70594-0089-02
		2 g	70594-0090-02
Ceftriaxone sodium	Piramal Critical Care	250 mg	66794-0211-42
		500 mg	66794-0212-42
		1 g	66794-0213-42
		2 g	66794-0214-42
		10 g	66794-0215-15
	Xellia Pharmaceuticals	250 mg	70594-0094-02
		500 mg	70594-0095-02
		1 g	70594-0096-02
		2 g	70594-0097-02
		10 g	70594-0098-01
Piperacillin sodium/tazobactam sodium	Civica, Inc.	3.375 g	72572-0576-10
		4.5 g	72572-0577-10
	Meitheal Pharmaceuticals	2.25 g	71288-0020-31
		3.375 g	71288-0030-31
		4.5 g	71288-0040-51
	Piramal Critical Care	2.25 g	66794-0216-41
		3.375 g	66794-0217-41
		4.5 g	66794-0218-41
	Xellia Pharmaceuticals	2.25 g	70594-0078-02
		3.375 g	70594-0079-02
		4.5 g	70594-0080-02

- Intravenous or intramuscular administration of a product for which sterility cannot be assured could result in serious system infections.
- To date, Astral has not received reports of adverse events relating to this issue.
- Contact Sedgwick (appointed company for Astral) at 1-888-719-5826 for questions regarding this
 recall



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews® is published by the Optum Rx Clinical Services Department.