



THE **MEDICINES** COMPANY®

VOLUNTARY RECALL of
ARGATROBAN INJECTION
50mg per 50mL
NDC 42367-203-07 (Single-use vial)
NDC 42367-203-84 (Carton of 10 single-use vials)

December 5, 2011

Dear Wholesale Partner,

Our supplier, Eagle Pharmaceuticals Inc., has issued a voluntary recall of all four (4) lots of Argatroban Injection, 50mg per 50mL ("Argatroban") from the market due to a potential for visible particulates.

The Medicines Company has not received any reports of adverse events related to this issue. However, due to the possible presence of visible particulates there is a risk of embolization/infarction to organs with potential organ complications.

Eagle Pharmaceuticals Inc. has directed The Medicines Company ("MDCO") to arrange for the return of the following lots from all services and facilities:

Lot Number	Expiration Date
V10189	Jan. 2013
V10191	Jan. 2013
V10194	Jan. 2013
V10223	Feb. 2013

During the investigation of the only product complaint, a visible particulate was discovered in a stability sample in one of the distributed lots. This discovery prompted a re-inspection of undistributed lots at the manufacturing site. Upon this re-inspection, a small number of visible particulates were discovered in several vials.

Eagle Pharmaceuticals Inc. is conducting this voluntary recall as a precautionary measure with the knowledge of the US Food and Drug Administration ("FDA"). This voluntary recall is being conducted nationwide at the pharmacy and distributor levels.

Upon receipt of this letter, please take the following actions:

- Immediately quarantine the Argatroban lots in your possession.
- Complete a count of the affected product lots in your inventory.
- Complete the attached Wholesaler Recall Response Form.
- Email the completed form to ArgatrobanRecall@icsconnect.com or fax to TMC Direct at (866) 860-3566.
- Include a copy of your debit memo with your Recall Response Form.



THE **MEDICINES** COMPANY®

TMC Direct will provide you with a return goods authorization and return goods instruction via email or fax. Third-party returns will NOT be accepted. TMC Direct will issue credit to your organization upon receipt and confirmation of returned cartons.

The Medicines Company will make reimbursement of reasonable and customary costs involved in this recall. Those costs should be submitted to Steve Wesley at steve.wesley@themedco.com.

Recall notification and instructions for returning product are being sent to affected hospital pharmacies. Hospitals are directed to return recalled product to TMC Direct, not to their respective wholesalers. If a hospital attempts to return Argatroban returns through the wholesale chain, please reject the return and direct the customer to contact The Medicines Company at argatrobanrecall@themedco.com or 615.893.6854.

Within **30-days**, please complete returns of the recalled product to TMC Direct.

Your contact at TMC Direct is Joe Macias.
Email: argatrobanrecall@icsconnect.com
Phone: (469)365-7463

Your contact at The Medicines Company is Steve Wesley.
Email: steve.wesley@themedco.com
Phone: (615)893-6854

Please feel free to contact me with any questions or concerns.

Sincerely,

Steve Wesley
Sr. Director, US Commercial Distribution



THE **MEDICINES** COMPANY®

Wholesaler Recall Response Form

Argatroban Injection - 50mg per 50mL

NDC 42367-203-07 (Single-use vial)

NDC 42367-203-84 (Carton of 10 single-use vials)

IMPORTANT: Immediately examine your inventory to identify products subject to the recall. To ensure accountability, it is imperative that this form be completed in its entirety and returned even if you do not have any of the affected product on hand.

Wholesaler Name *	
Wholesaler Address	
Wholesaler City, ST, Zip*	
Completed By (Name and Title) *	
Phone: *	
Fax:	
E-mail *	
Debit Memo Number *(Please be sure to include a copy of the Debit Memo)	

We do not have any of the affected product lots in our inventory.

If you do not have the affected product lots in your inventory, you do not need to complete the remainder of the form. Once the section above is completed, simply sign and date at the bottom of page 2 and return the form using the e-mail or fax listed below.

If you do have the affected product lots in your inventory, please complete the sections below.

We are returning the product as indicated below:

Response Form Page 1 of 2



THE **MEDICINES** COMPANY®

Wholesaler Name *	
Wholesaler City	

Product Description	Lot	Expiration Date	Full Carton QTY* NDC: 42367-203-84
Argatroban Injection 50mg/50mL	V10189	01/31/2013	
Argatroban Injection 50mg/50mL	V10191	01/31/2013	
Argatroban Injection 50mg/50mL	V10194	01/31/2013	
Argatroban Injection 50mg/50mL	V10223	02/28/2013	

Once completed, the form can be e-mailed to ArgatrobanRecall@icsconnect.com or faxed to TMC Direct at (866) 860-3566.

I affirm that I have followed the instructions on this form and that the stated count is correct and the recalled product is being returned.

Wholesaler Signature

Date

**** These are required fields. Failure to include this information could result in a delay in processing your return authorization.***