

RETAVASE® (reteplase) for injection, 10 units/vial

Return and Replacement Program



This Return and Replacement Program sets forth the terms, conditions and eligibility for the Chiesi USA, Inc. (“Chiesi”) product, Retavase (“Product”). Product purchased directly and indirectly must be returned directly to Chiesi’s designated third-party returned goods processor in order to be eligible for replacement. Chiesi reserves the right to refuse replacement when returned through alternate channels.

If Product was purchased through your wholesaler and is not eligible for the Return and Replacement Program, the Product should be returned through your wholesaler or reverse distributor, where applicable.

Return and Replacement Program

When Product prescribed for a labeled indication is spoiled and unable to be administered, the Product may be eligible for replacement through this Chiesi Return and Replacement Program. If Product has been administered to a patient or billed to a patient or payor, including a federal health care program, a replacement is not available. Furthermore, replacement can only be made for the same Product that the customer had intended to use had such Product not spoiled.

- Spoiled Product includes:
 - Product that was mishandled, dropped or broken
 - Product that was inappropriately stored or refrigerated (or frozen)
 - Product that was mixed in error
 - Product that was mixed but not administered due to an unforeseen patient condition
- Only single units are eligible for replacement
- The entire kit should be returned when practicable
- To request replacement for spoiled Product, please contact Chiesi Customer Service at 1-888-466-6503 to obtain a Return Authorization Number (“RA Number”)
- To obtain an RA Number:
 - You will need the following information: NDC, Lot Number, Expiration Date, Quantity, Purchase Price, Debit Memo Number, Billing Address, Shipping Address, Contact Information and Reason for Return; and,
 - You will need to complete the Return and Replacement Program form and affidavit that will be provided by Chiesi Customer Service. Proof of purchase from an authorized distributor and a picture of the spoiled Product may be required
- Fax the form, proof of purchase, picture (if required) and affidavit to 1-877-302-1743 or email to US.CustomerService@chiesi.com
- Chiesi approval required:
 - If approved, Chiesi Customer Service will provide instructions for how to return the spoiled Product
 - Requests must be made within ten (10) business days of the date the spoilage occurred
 - The request may take up to seven (7) business days to review
 - Upon Chiesi approval, replacement Product will ship within ten (10) business days following receipt of the spoiled Product
- The RA Number must be clearly written on the outside of the parcel containing the returned Product. The parcel must include copies of the original shipping document and debit memo
- Product must be returned within thirty (30) days of receipt of the RA Number
- Shipping and transportation charges must be prepaid by the customer

Returns for reasons related to Product quality (for example, discolored Product, etc.) or an adverse event should be reported to Chiesi’s Medical Information Department at 1-888-661-9260 or US.Medical@chiesi.com

Returning Product

Customers are liable for the Product until Chiesi’s returned goods processor identifies it as an appropriate return, which may take up to fourteen (14) business days after receiving all information related to the claim.