

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 or when Product expires, the Product may be eligible for replacement through this Chiesi Return and Replacement Program. Product that has been administered to a patient or billed to a patient or payor (including a federal health care program) is not eligible for replacement under this Program. Furthermore, replacement can only be made for the same Product that the customer had intended to use had such Product not spoiled or expired.

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.

Expired Product includes:

- Product purchased from an Authorized Wholesaler that is within six (6) months post-Expiration Date.

Return and Replacement Process

- To request replacement for spoiled or expired Product under this Program, please contact Chiesi Customer Service at **1-888-466-6503** to obtain a Return Authorization Number (“RA Number”).
- Submission of the following information is required:
 - NDC, Lot Number, Expiration Date, Quantity, Purchase Price, Reason for Return, Billing Address, Shipping Address, Contact Information, Proof of Purchase from an Authorized Distributor, and a Photo of the Spoiled Product.
- Please submit all required information either via fax (**1-877-302-1743**) or email (US.CustomerService@chiesi.com).

General Terms and Conditions

- All requests are subject to approval by Chiesi USA, Inc.
- Requests due to spoilage must be made within ten (10) business days of the date the spoilage occurred.
- Requests due to expiration must be made within six (6) months of the labeled Expiration Date.
- The request may take up to seven (7) business days to review. Upon Chiesi’s approval, replacement Product will ship within ten (10) business days following receipt of the spoiled or expired 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.
- 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.

Returns for Quality or Adverse Events

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