

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 75-684

FINAL PRINTED LABELING

Keyline does not print.

408-01 50 mL PHARMACY BULK VIAL
FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS AND USUAL ADULT DOSAGE:
See package insert.

*Each mL contains 10 mg of famotidine and the following inactive ingredients: L-aspartic acid 4 mg, mannitol 20 mg, and Water for Injection, q.s., 1 mL. Benzyl alcohol 9 mg added as preservative.

Store at 2° to 8°C (36° to 46°F).
Once the container closure has been punctured, withdrawal of the contents should be completed without delay. THE ENTIRE CONTENTS OF THE VIAL SHOULD BE DISPENSED WITHIN 4 HOURS OF INITIAL ENTRY.

Date Entered: _____ Time of Entry: _____

Manufactured by:
Bedford Laboratories™
Bedford, OH 44146

APPROVED
APR 16 2001

Note: Keyline does not print.

FAMOTIDINE INJECTION

PHARMACY BULK PACKAGE
NOT FOR DIRECT INFUSION

MUST BE DILUTED PRIOR TO IV USE.
Do not dispense as a unit.

500 mg 50 mL

20 mg/2 mL
Rx ONLY

NDC 55390-026-01 50 mL PHARMACY BULK VIAL
FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS AND USUAL ADULT DOSAGE:
See package insert.

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Date Entered: _____ Time of Entry: _____

Manufactured by:
Ben Venue Labs, Inc.
Bedford, OH 44146

BEDFORD
LABORATORIES

Manufactured for:
Bedford Laboratories™
Bedford, OH 44146

APPROVED

APR 16 2001

Ben Venue
PRINTED SIDE
C011294HA

75-684
4/16/01

1¹³/₁₆ 1¹³/₁₆



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NDC 55390-026-01
50 mL PHARMACY BULK VIAL

FAMOTIDINE INJECTION

PHARMACY BULK PACKAGE—
NOT FOR DIRECT INFUSION

MUST BE DILUTED PRIOR TO IV USE.
Do not dispense as a unit.

500 mg/50 mL*

20 mg/2 mL
Rx ONLY.



FOR THE PREPARATION OF INTRAVENOUS SOLUTIONS and USUAL ADULT DOSAGE: See accompanying circular.

Store at 2° to 8°C (36° to 46°F).

If solution freezes, bring to room temperature; allow sufficient time to solubilize.

Once the container closure has been punctured, withdrawal of the container contents should be completed without delay. THE ENTIRE CONTENTS OF THE VIAL SHOULD BE DISPENSED WITHIN 4 HOURS OF INITIAL ENTRY.

NDC 55390-026-01
50 mL PHARMACY BULK VIAL

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Bedford, OH 44146

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LOT
EXP

FAM-PBC00C

Format Number: 77369 #086A
Black
478 Brown