LABELLING

We shall use the labels shown overleaf in the U.K. but they will be overprinted with our name, Bayer U.K. Ltd., Pharmaceutical Division, address Haywards Heath, Sussex, and the product licence number.

NDC

ANTIHEMOPHILIC FACTOR (HUMAN)

Koāte™

CUTTER

Lyophilized Powder Code

Dosage: See Direction Sheet

Store at 2° to 8°C. (35° to 46°F.).

CONTENTS:

One bottle of Koāte™
20 ml. Sterile Water for Injection, U.S.P.
One sterile filter needle for reconstitution

No Preservative

For Intravenous Administration Only

Sterile - Non-Pyrogenic

U.S. Gov't. Lic. No. 8

CUTTER Laboratories, Inc., Berkeley, Calif. 94710, U.S.A.

OPEN OTHER END

CARTON LABEL

FRONT PANEL

For reconstitution with
10 ml Sterile Water for
Injection, U.S.P.

ANTIHEMOPHILIC FACTOR (HUMAN)

Koāte™

CUTTER

Lyophilized Powder

Code

Lot

Exp.

AHF Units *

Grams Protein *

HEPATITIS DANGER
SEE DIRECTION
SHEET

INSTRUCTIONS - RECONSTITUTION

1. Transfer 10 ml. of diluent to the bottle of lyophilized Koāte™.
2. After the diluent has been added, gently swirl the mixture until the powder is completely dissolved. Avoid foaming.
3. Withdraw the Koāte™ solution through the filter needle which is enclosed.
4. Do not refrigerate after reconstitution.
5. Administer promptly after reconstitution within 3 hours.
6. See Direction Sheet for detailed instructions.

BACK PANEL

Not returnable for credit or exchange.

When reconstituted with 10 ml. Sterile Water for Injection, U.S.P. the solution contains 1% Dextrose, U.S.P. and is slightly hypertonic.

(anhydrous)

WARNING: Since the presence or absence of the virus of hepatitis in Koāte™ cannot be proven with absolute certainty, the presence of such virus should be assumed and the hazard of administering Koāte™ should be weighed against the medical consequences of withholding the use of Koāte™.

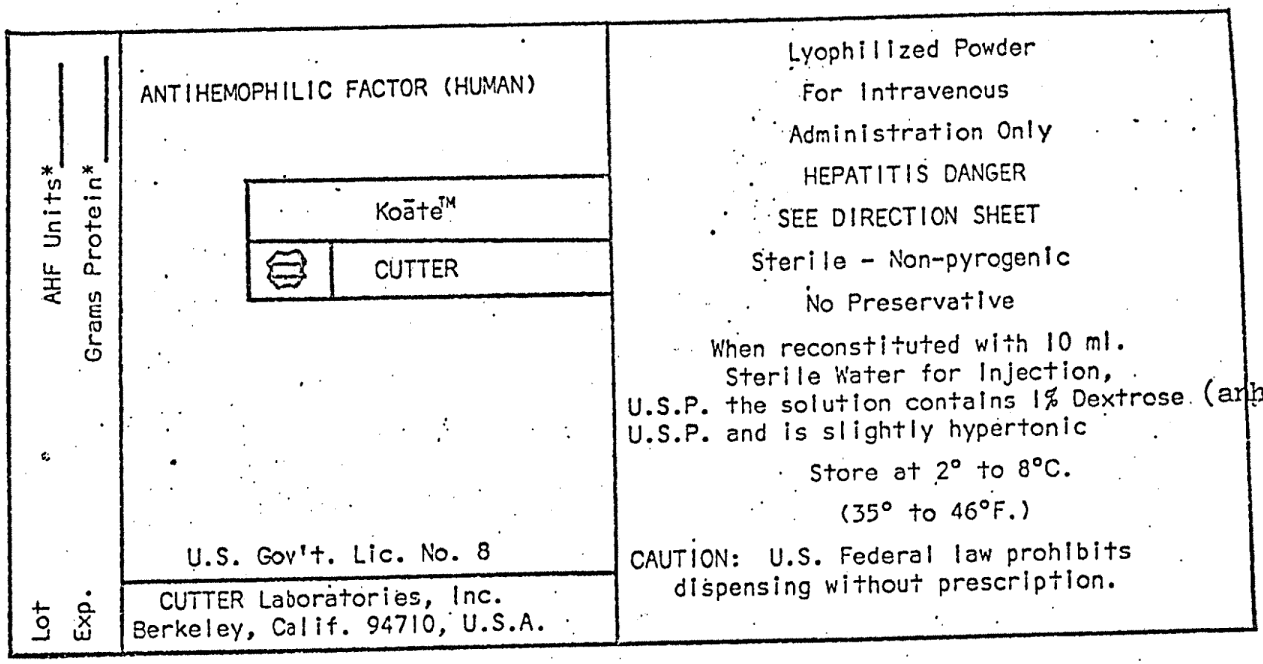
CAUTION: U.S. Federal law prohibits dispensing without prescription.

SIDE PANEL

CARTON LABEL

For reconstitution with 10 ml.
Sterile Water for Injection, U.S.P.

*To be entered after potency assay is completed.



CONTAINER LABEL

For Reconstitution with 10 ml.
Sterile Water for Injection, USP

* To be entered after potency assay is completed.

10/75

NDC

ANTIHEMOPHILIC FACTOR (HUMAN)

Koāte™

CUTTER

Lyophilized Powder Code

Dosage: See Direction Sheet

Store at 2° to 8°C. (35° to 46°F.).

CONTENTS:

One bottle of Koāte™
20 ml. Sterile Water for Injection, U.S.P.
One sterile filter needle for reconstitution

No Preservative

For Intravenous Administration Only

Sterile - Non-Pyrogenic

U.S. Gov't. Lic. No. 8

CUTTER Laboratories, Inc., Berkeley, Calif. 94710, U.S.A.

OPEN OTHER END

CARTON LABEL

FRONT PANEL

For reconstitution with
20 ml Sterile Water for
Injection, U.S.P.

ANTIHEMOPHILIC FACTOR (HUMAN)

Koate™

CUTTER

Lyophilized Powder

Code

Lot

Exp.

AHF Units *

Grams Protein*

HEPATITIS DANGER
SEE DIRECTION
SHEET

INSTRUCTIONS - RECONSTITUTION

1. Transfer 20 ml. of diluent to the bottle of lyophilized Koate™.
2. After the diluent has been added, gently swirl the mixture until the powder is completely dissolved. Avoid foaming.
3. Withdraw the Koate™ solution through the filter needle which is enclosed.
4. Do not refrigerate after reconstitution.
5. Administer promptly after reconstitution within 3 hours.
6. See Direction Sheet for detailed instructions.

BACK PANEL

Not returnable for credit or exchange.

When reconstituted with 20 ml. Sterile Water for Injection, U.S.P. the solution contains 1% Dextrose, U.S.P. and is slightly hypertonic.

(anhydrous)

WARNING: Since the presence or absence of the virus of hepatitis in Koate™ cannot be proven with absolute certainty, the presence of such virus should be assumed and the hazard of administering Koate™ should be weighed against the medical consequences of withholding the use of Koate™.

CAUTION: U.S. Federal law prohibits dispensing without prescription.

SIDE PANEL

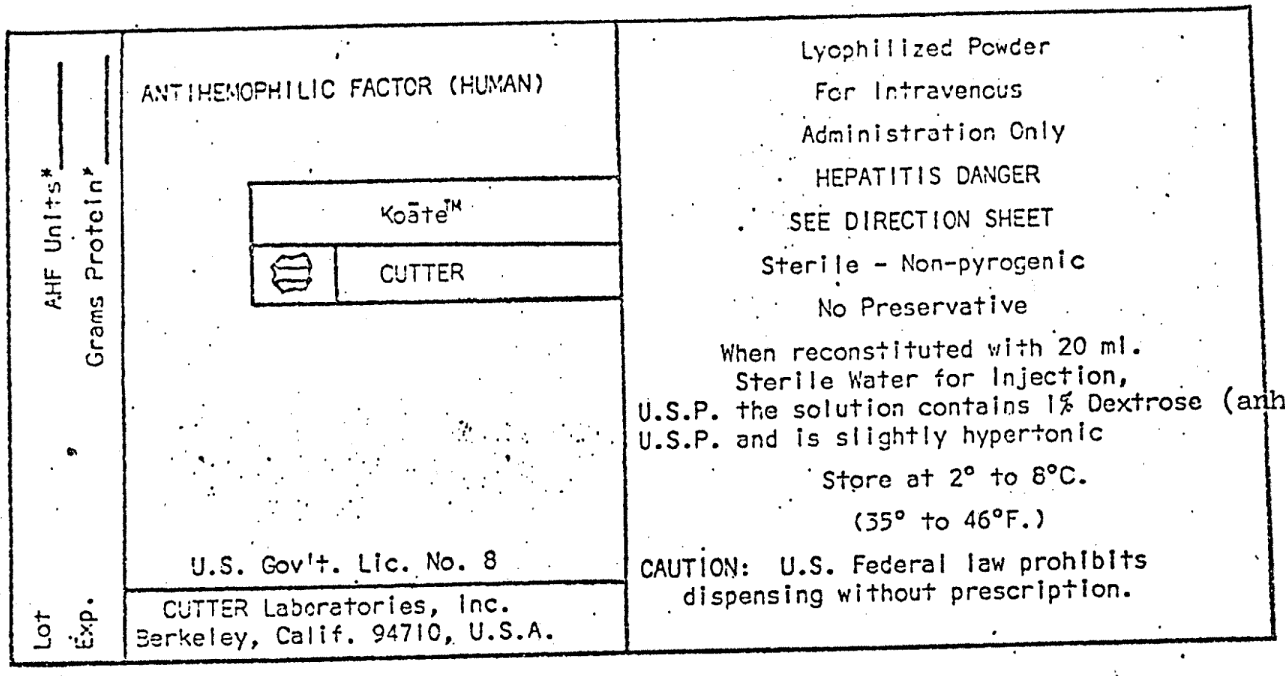
CARTON LABEL

For reconstitution with 20 ml.
Sterile Water for Injection, U.S.P.

*To be entered after potency assay is completed.

10/73

12-15/4



CONTAINER LABEL

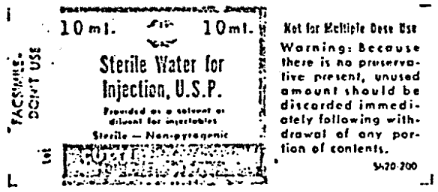
For Reconstitution with 20 ml.
Sterile Water for Injection, USP

*To be entered after potency assay is completed.

10/73

DILUENT CONTAINER LABEL

FILL: 10 ml.



DILUENT CONTAINER LABEL

Fill: 20 ml.