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)

KoāteTM

(3)

CUTTER

Lyophilized Powder

Code

Dosage: See Direction Sheet

Store at 2° to 8°C. (35° to 46°F.).

CONTENTS:

One bottle of KoāteTM
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.

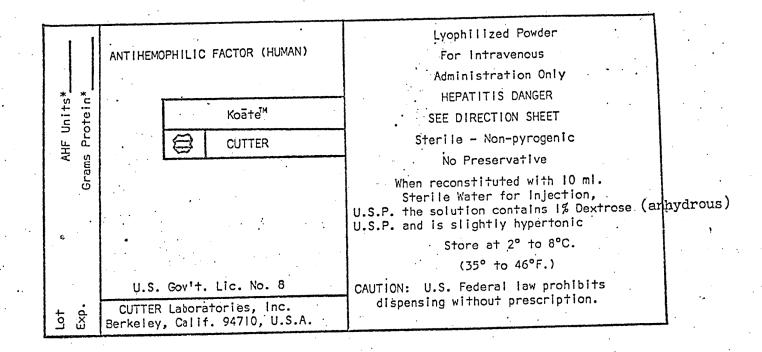
OPEN OTHER END

CARTON LABEL

FRONT PANEL

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

ə	E Koāte ^{IN} Koāte ^{IN} CUTTER CUTTER G CUTTER COTTER Coder Coder	Lot Exp. AHF Units *	IS DANGER		
	INSTRUCTIONS - RECONSTITUTION				
1. Transf	er 10 ml. of diluent to the bottle of lized Koāte TM .	í	Not returnable for credit or exchange.		
swirl	the diluent has been added, gently the mixture until the powder is tely dissolved. Avoid foaming.	When reconstituted with 10 ml. Sterile Water for Injection, U.S.P. the solution contain 1% Dextrose, U.S.P. and is slightly hypertonic. (anhydrous) WARNING: Since the presence or absence of the virus of hepatitis in Koāte TM cannot be proven with absolute certainty, the presence of such virus should be assumed and the hazard of administering Koāte TM should be weighed against the medical consequences of withholding the use of Koāte TM .			
3. Withdr	Withdraw the Koate TM solution through the filter needle which is enclosed. Do not refrigerate after reconstitution.				
4. Do not					
	ster promptly after reconstitution a hours.				
6. See Di	rection Sheet for detailed instruction	s.	CAUTION: U.S. Federal law prohibits dispensing without prescription.		
	DACK DANEI				
,	BACK PANEL CARTON LABEL		SIDE PANEL		
For	CARTON LABEL reconstitution with 10 ml. rile Water for Injection, U.S.P.				



CONTAINER LABEL

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

* To be entered after potency assay is completed.

. NDC

ANTIHEMOPHILIC FACTOR (HUMAN)

KoāteTM

CUTTER

Lyophilized Powder

Code

Dosage: See Direction Sheet

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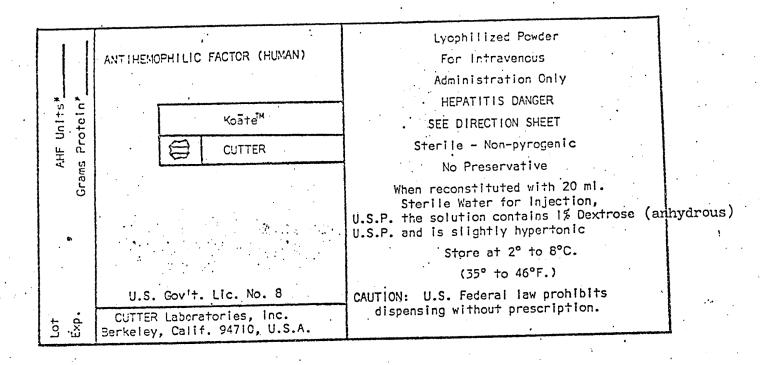
OPEN OTHER END

CARTON LABEI

FRONT PANEL

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

	()		•
	* ANTIHEVORHILIC FACTOR (HUMAN) ***********************************	HEPATITIS DANGER SEE DIRECTION SHEET	10/73
	INSTRUCTIONS - RECONSTITUTION		•
1.	Transfer 20 ml. of diluent to the bottle of lyophilized Kolte.	Not returnable for credit or exchange.	
3.	After the diluent has been added, gently swirl the mixture until the powder is completely dissolved. Avoid foaming. Withdraw the Koūte™ solution through the filter needle which is enclosed. Do not refrigerate after reconstitution. Administer promptly after reconstitution within 3 hours. See Direction Sheet for detailed instructions.	When reconstituted with 20 ml. Sterile Water for Injection, U.S.P. the colution contains 1% Dextrose, U.S.P. and is slightly hypertonic. (anhydrous) WARNING: Since the presence or absence of the virus of hepatitis in Kolte TM cannot be proven with absolute certainty, the presence of such virus should be assumed and the hazard of edministering Kolte TM should be weighed against the medical consequences of withholding the use of Kolte TM .	
		CAUTION: U.S. Federal law prohibits dispensing without prescription.	
	BACK PANEL		-
	CARTON LABEL For reconstitution with 20 ml. Sterile Water for Injection, U.S.P.	SIDE PANEL	12-15/4
*To b	e entered after potency assay is completed.		
	·		1 1



CONTAINER LABEL

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

*To be entered after potency assay is completed.

DILUENT CONTAINER LABEL

FIII: 10 ml.

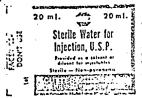
10 ml. 10 ml.

Sterile Water for Injection, U.S.P.

at far Kellifle Dase Base arming: Because ere is no preservatre present, unused mount should be seconded immedially following withawai of any poron of contents.

DILUENT CONTAINER LABEL

Fill: 20 ml.



let far Mellijke Base Ess
Varning: Because
here is no proservaive present, unused
mount should be
istarded immeditely following withrowal of ony porion of contents.