KOATE LABELLING

PROPOSED NEW TEXT COMPLYING WITH U.K. REGULATIONS

A. Vial Label - 250, 500, 1000, 1500 Unit Packs.

K O A T E(R)

Dried Factor VIII Fraction

For intravenous administration only
Contains no preservative
Sterile - non-pyrogenic

To be diluted with 10ml (20ml) (40ml) Water for Injection

HEPATITIS DANGER - SEE INSERT LEAFLET

Store at 2° to 8°C
Allow to warm to 20°-30°C before reconstitution

If a gel forms on reconstitution, do not use

Electrolyte Concentration

Citrate	Not more than 55 mmol/l
Sodium	Not more than 200 mmol/l
Chloride	Not more than 200 mmol/l

Fibrinogen ..... Not more than 0.25gm/10ml

PL 0055/0065

POM

Cutter, Division of Miles Laboratories Limited, Stoke Court, Stoke Poges, Slough, SL2 4LY, England.

Mfd. by : Cutter, Division of Miles Laboratories Inc., Berkeley, C.A., U.S.A.

Batch No. XXXX

XXX I.U.

Expiry Date XXXX

XXX Grams Protein

Date Removed From Refrigerator _____

To be deleted from text:

- U.S. Govt. Licence No. 8
- Elkhart address (where used)

B. Carton Label - 250, 500, 1000, 1500 Unit Packs.

K O A T E(R)

Dried Factor VIII Fraction

Dosage : See Insert Leaflet

Store at 2° to 8°C

Contents:

One bottle of Koate
10ml (20ml) (40ml) Sterile Water for Injection
One sterile filter needle for reconstitution
One sterile transfer needle

Contains no preservative
For intravenous administration only
Sterile - non-pyrogenic

Electrolyte Concentration

Citrate ..... Not more than 55 mmol/l
Sodium ..... Not more than 200 mmol/l
Chloride ..... Not more than 200 mmol/l

Fibrinogen ..... Not more than 0.25gm/10ml

PL XXXX

POM

Batch No. XXXX

XXX I.U.

Expiry Date XXXX

XXX Grams Protein

Date Removed From Refrigerator _____

HEPATITIS DANGER - SEE INSERT LEAFLET

Instruction - Reconstitution

1. Transfer 10ml of diluent to bottle of lyophilised 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 Insert Leaflet for detailed instructions.

When reconstituted with 10ml (20ml) (40ml) Sterile Water for Injection the solution contains 1% Dextrose and is slightly hypertonic.

This product is prepared from human venous plasma. Each individual unit of plasma has been found nonreactive for hepatitis B surface antigen using a U.S. Federally approved test.

WARNING : KOATE(R) CONCENTRATE IS A PURIFIED DRIED FRACTION OF POOLED PLASMA OBTAINED FROM MANY DONORS. THE PRESENCE OF HEPATITIS VIRUS SHOULD BE ASSUMED AND THE HAZARD OF ADMINISTERING KOATE(R) CONCENTRATE SHOULD BE WEIGHED AGAINST THE MEDICAL CONSEQUENCE OF WITHHOLDING IT, PARTICULARLY IN PERSONS WITH FEW PREVIOUS TRANSFUSIONS OF BLOOD AND PLASMA PRODUCTS.

Cutter, Division of Miles Laboratories Limited, Stoke Court, Stoke Poges, Slough, SL2 4LY, England.

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To be deleted from carton text:

- U.S. Govt. Licence No. 8
- CAUTION : U.S. Federal law prohibits dispensing without prescription.
- Elkhart address (where used).

C. Sterile Water for Injection

Sterile Water for Injection

Provided as a solvent or diluent for injectables

Sterile - Non-pyrogenic

10ml, (20ml), (40ml)

Not for Multiple Dose Use

Warning: Because there is no preservative present, unused amount should be discarded immediately following withdrawal of any portion of the contents.

POM

Batch No. xxxx

Expiry Date xxxx

Cutter Division of Miles Laboratories Ltd., Stoke Court, Stoke Poges, Slough SL2 4LY, England

Mfd. by: Invenex Laboratories Gibco Div., The Dexter Corp., Chagrin Falls, OH 44022, U.S.A.