

HT Falute Guel Ch
Rorer



Health Care Limited

To: V. Brzeksi

C0000114

From: C.R. Bishop

Date: 10th June 1986.

Subject: HTLV-III ANTIBODY TESTING LABELS

Ref: CRB/BAK

Copies to:

A. Sheppard
J. Moore
R.B. Christie
P. ^{ris}
C. Collins
S. Gould
P. Bradford
C. Bloor
Master
Day
File

Dear Vitek,

Further to our previous correspondence, I enclose a copy of Cutter's packaging (one of our competitors), from which you can see they are now adopting the suggesting labelling.

Please advise whether there is any progress with regard to our own labelling. If necessary, and to save time, I suggest a label be produced just for the outers containing the 10 vials, although ideally each individual vial should be so labelled.

Your early comments would be appreciated.

Thank you.

GRO-C

R. B. C.

11 JUN 1986

C.R. Bishop.

Inter office memorandum

ARMOUR002934

ARMO0000534_0001

C0000115

This product has been prepared from large pools of human venous plasma collected from many donors. Each individual unit of plasma and each lot of final product was tested and found nonreactive for hepatitis B surface antigen (HBsAg) by an FDA approved method.

WARNING: KOATE[®] HT IS A PURIFIED DRIED FRACTION OF POOLED PLASMA OBTAINED FROM MANY DONORS. THE PRESENCE OF HEPATITIS VIRUSES SHOULD BE ASSUMED AND THE HAZARD OF ADMINISTERING KOATE[®] HT SHOULD BE WEIGHED AGAINST THE MEDICAL CONSEQUENCE OF WITHHOLDING IT, PARTICULARLY IN PERSONS WITH FEW PREVIOUS TRANSFUSIONS OF BLOOD OR BLOOD PRODUCTS.

Reconstitute with 10 mL Sterile Water for Injection.
Contains Glycine.
Not Returnable For Credit or Exchange.

Each individual unit of plasma has been tested for antibody to HTLV-III by an FDA approved method and found nonreactive.

14-0007-000

Lyophilised Powder

Directions For Use: See Insert Leaflet.

Store at 2-8°C. DO NOT FREEZE.

CONTENTS:

One Bottle of Koate[®] HT

10 mL Sterile Water for Injection

One sterile filter needle

One sterile double-ended transfer needle

Contains no preservatives

For intravenous administration only

Sterile - Nonpyrogenic

U.S. Patent No. 3,644,412

Product License No. US-0107

Mfd. by Cutter Biological
Berkeley, CA 94710 USA, Division of
Miles Laboratories, Inc., Elkhart, IN 46514 USA
Dist. by Cutter Division of Miles Laboratories, Ltd.
Stoke Court, Stoke Poges, Slough SL2 4LY
Buckinghamshire, England



GRO-C