BLOOD PRODUCTS LABORATORY, DAGGER LANE, ELSTREE, HERTS., WD6 3BX. Tel: 01-953 6191

Clinical response to heated high-purity factor VIII concentrate, 8Y

DELIVERY, ADVICE AND ACKNOWLEDGEMENT

Batch 8Y 3312

Consignment of 50 vials, each 205 iu VIII, dispatched 4/8/86

This consignment of unlicensed product is made to the prescription of Dr. P. Peel for treatment under his/her direction of the patient(s) named below:

A brief description of the product and instructions for use are enclosed in each box of 10 vials. Should you see any untoward effect attributed to this batch, or any apparent failure to correct bleeding, please telephone Dr. T.J. Snape, Head of QC, BPL or Dr. J.K. Smith, PFL, Oxford (0865 62002).

The physician should assess and record the efficacy of at least the first infusion of this product received by each patient, take blood samples for tests of HTLV III antibody and undertake follow-up for possible infection with hepatitis viruses.

SUMMARY OF ACTION REQUIRED BY PHYSICIAN IN CHARGE (see protocol for details)

Now —

Please acknowledge that you have received the consignment of factor VIII and that you agree to the proposals for recording infusion data and follow-up of virus transmission in appropriate patients. Sign the attached duplicate of this page, retaining your own copy and post to Dr. J.K. Smith, PFL.

When patient is first infused with this batch

Before the first infusion, take a sample for factor VIII assay and HTLV III antibody. Take the samples indicated in Part 2 of the follow-up form for LFTs, hepatitis markers, and replicates for possible retrospective testing for HAV, CMV and EBV.

Enter patient's infusion and factor VIII recovery data on Part 1.

Enter patient identification and first infusion date on Part 2, and record the results of tests listed in the "pre" column.

On completion of this course of treatment

Complete all entries on Part 1, using further copies of the follow-up form (marked EXTENSION) if necessary, photocopy the page and post to Dr. J.K. Smith, PFL.

At (or near) stated intervals following first infusion

Take plasma samples, initiate tests and distribute samples as indicated in the accompanying protocol, and record results on Part 2. At 8, 24 and 52 weeks (i.e. at the end of each sub-table), photocopy the page and post to Dr. J.K. Smith, PFL.

If the patient is treated with another batch of this or another product during the follow-up period

Enter on Part 1 or Part 2 "Remarks" and see accompanying protocol.

If the patient shows laboratory or clinical evidence of virus infection

See accompanying protocol.

I acknowledge receipt of this consignment. This constitutes a prescription for the patients named above.

_____ Physician in charge