

REVION HEALTH CARE (UK) LIMITED

Armour Pharmaceutical
Company Limited

INTER OFFICE MEMORANDUM

BERK
Pharmaceuticals Ltd.

TO : MR. C. BLATCHFORD

FROM : R. B. CHRISTIE

SUBJECT : REPORTED ADVERSE REACTION TO FACTORATE

DATE: AUGUST 17, 1984

REF: RBC/EB/5087

COPIES TO :

Mr. P.B. Lloyd
Mr. C.J. Collins
Mr. C.R. Bishop

We have received a "Suspected Adverse Reaction Report" on Factorate from Dr. Lee at St. George's Hospital, London. A patient with severe haemophilia with VIII inhibitors who is on Factorate therapy and FEIBA (Immuno) has developed clinical hepatitis confirmed with HBSAG positive on 21/6/84.

He has received Factorate as follows:

<u>BATCH</u>	<u>DOSE</u>	<u>DATE STARTED</u>	<u>DATE STOPPED</u>
X37305	33,525 u	16/10/83	9/2/84
X21902	16,125 u	9/2/84	5/3/84
X52609	50,140 u	9/3/84	31/5/84
X52509	4,050 u	4/6/84	continuing

He also received FEIBA 49,000 units from 12/10/83 to 5/6/84. The patient is now clinically recovered.

The distribution of these batches has been quite wide, including the Royal Free Hospital, Royal Sussex County, Brighton, Wessex B.T.C., Lewisham Hospital, Leeds B.T.C., Churchill Hospital, William Harvey Hospital, Ashfield, King's College Hospital, Hammersmith Hospital and a number of private individuals at home and abroad. No further reports of hepatitis or other adverse reactions have been reported to us to date.

The St. George's case does appear to be an isolated incident and may not be associated with the Factorate. Hence further action does not seem to be indicated at present. We will keep careful watch for any reports of adverse reactions to any of these batches and advise you should any occur.

GRO-C

R. B. CHRISTIE