

REVIION HEALTH CARE (UK) LIMITED

St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG
Telephone: Eastbourne (0323) 21422/641144 Telex: 87141/877052

RBC/EB/5095

August 20, 1984

The Medical Assessor,
Committee on Safety of Medicines,
Market Towers,
1, Nine Elms Lane,
Vauxhall,
LONDON, SW8 5NL.

Dear Sir,

I enclose a Report on Suspected Toxicity or Side Effects covering jaundice, raised LFTs and positive HBSAG on a young haemophilia patient at St. George's Hospital, London, following treatment with Factorate and FEIBA (Immuno).

The batches of Factorate involved in the report have been widely distributed and only one other report of positive HBSAG has just been reported to us relating to two of the batches used on this patient.


The results of the investigation into the second report will be notified to you shortly.

Yours faithfully,

GRO-C

R. B. CHRISTIE,
Director of Clinical Sciences

Enc.

 **Armour Pharmaceutical
Company Limited**

Registered Office: St. Leonards House, St. Leonards Road, Eastbourne, Sussex BN21 3YG

Registered in England No. 1615960

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IN CONFIDENCE

CSM/AR/IND
B/M272/086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

NOTES FOR GUIDANCE

1. For all drugs, please record serious or unusual reactions. For new drugs record all reactions.
2. Record, on the top line, the drug suspected of causing harmful effects to the patient at normal dosage.
3. Record all other drugs, including self-medication, taken in the previous 3 months. With congenital abnormalities, record all drugs taken during pregnancy.
4. Please do not be deterred from reporting because some details are not known.

Name of Patient: _____
 Required in confidence to
 show linkage with other
 reports for same patient)

From (Name and address):
Company doctor or other representative of product
licence holder— R. B. CHRISTIE,
DIRECTOR, CLINICAL SCIENCES, REVLOX HEALTH
CARE (U.K.) LTD., ST. LEONARD'S HOUSE,
ST. LEONARD'S ROAD, EASTBOURNE, EAST SUSSEX.
Signed: GRO-C Date: 20/8/84

SEX
MALE

Age or Date
of Birth
16

Weight
if known
60 KG

Name of patient's own doctor (and address if known):
DR. R. LEE, FOR PROFESSOR P.T. FLUTE,
ST. GEORGE'S HOSPITAL,
LONDON. SW17 0RE.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTORATE X37305	I.V.	33,525 U	16/10/83	9/2/84	SEVERE HAEMOPHILIA WITH
FACTORATE X21902	I.V.	16,125 U	9/2/84	5/3/84	FACTOR VIII INHIBITORS
FACTORATE X52609	I.V.	50,140 U	9/3/84	31/5/84	CONTINUING
FACTORATE X52509	I.V.	4,050 U	4/6/84		
FEIBA (IMMUNO)	I.V.	49,000 U	12/10/83	5/6/84	
*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal; recovered)
POSITIVE HBsAg					
JAUNDICE, RAISED LIVER FUNCTION TESTS.					
CLINICAL HEPATITIS			JUNE '84		RECOVERED

Additional Notes

THESE BATCHES OF FACTORATE HAVE BEEN DISTRIBUTED TO ELEVEN OTHER HOSPITALS, AND TO PHARMACIES ALSO ABROAD. WE HAVE JUST RECEIVED A REPORT OF SINGLE POSITIVE HBsAG INVOLVING X21902 AND X52509 AMONG OTHER BATCHES OF FACTORATE, WHICH IS BEING FOLLOWED UP. NO OTHER REPORTS OF SUSPECTED ADVERSE EFFECTS FROM THESE BATCHES HAVE BEEN RECEIVED.

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