

REVION HEALTH CARE (UK) LIMITED

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

RBC/EB/6939

January 18, 1985

Adverse Reactions Monitoring Unit,
Committee on Safety of Medicines,
Market Towers,
1, Nine Elms Lane,
LONDON, SW8 5NQ.

Dear Sirs,

I enclose a Report on Suspected Toxicity or Side Effects relating to a report of Hepatitis B occurring in a patient being treated with Factorate Batches X47408 and Y67101.

Both of these batches have been widely distributed throughout the U.K. and probably are all administered to patients. We have not, to date, received any further reports of hepatitis or abnormal liver function tests related to their use.

We will, of course, be alert to any adverse reports involving these two batches of Factorate and will advise you accordingly should they occur.

Yours sincerely,

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

cc: Mr. C.J. Collins
Mr. C.R. Bishop
Mr. P.B. Lloyd
Mr. C. Blatchford

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CSM/AR/IND
B/M272/086

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

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.

From (Name and address):
Company doctor or other representative of product
licence holder— R.B. CHRISTIE
REVLOX HEALTH CARE (U.K.) LTD.
ST. LEONARD'S HOUSE, ST. LEONARD'S ROAD
EASTBOURNE, EAST SUSSEX

Date: 18/1/85

Weight
if known

NOT KNOWN

Name of patient's own doctor (and address if known):
DR. G. SAVIDGE, CONSULTANT HAEMATOLOGIST
ST. THOMAS' HOSPITAL, LONDON, SE1.

*For Vaccines give Batch No.)

THE PATIENT HAD NO PREVIOUS HISTORY OF HEPATITIS NOR ANY KNOWN CONTACT.

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