



Armour Pharmaceutical Company Limited

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Our Ref. PAG/SY

27 th November 1978

The Medical Assessor
Committee on Safety of Medicine
Finsbury Square House
33-37A Finsbury Square
London
EC2A 1PP

Dear Sir

FACTORATE BATCH R8212

Please find enclosed two Yellow Forms reporting two cases of hepatitis with Factorate batch R8212.

As you can see, both cases were reported by Professor Ingram's unit at St Thomas' Hospital. Plans are in hand to re-test the batch for hepatitis B antigen and we will let you know the results when they are available.

If there is any further information you require, please do not hesitate to contact us.

Yours faithfully

GRO-C

Pauline A Goldsmith, B Sc, Dip Inf Sci
Medical Services Manager

C.c. Mr. K. W. Fitch
Mr. D. Ferguson
Mr. C. Bishop

Directors
W. F. Thompson (Chairman), K. W. Fitch (Vice-Chairman), R. J. Sedgwick, J. R. Jenkins, Dr. W. S. Morris
R. B. Brinton (USA), T. J. C. van Schelven (USA), L. A. Dorian (USA)

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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

300 327

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
allow linkage with other
reports for same patient)

(St. Thomas' Hospital No. [REDACTED])

From (Name and address):

Company doctor or other representative of product
licence holder— Dr. Wm. Sim. Munro,
Armour Pharmaceutical Company Ltd.,
Hampton Park,
Eastbourne, East Sussex.Signed: **GRO-C**

Date: 24/11/78

Sex

Male

Age or Date
of Birth

28

Weight
if known

95 kg

Name of patient's own doctor (and address if known):

Professor G. I. C. Ingram,
Department of Haematology,
Louis Jenner Laboratories,
St. Thomas' Hospital, Medical School, London.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTORATE					
Batch R8212	i/v	275	28.6.78		Haemophilia post dental extraction
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
Has become HBs Ag positive - no clinical jaundice			17.10.78		
No liver function test results available yet.					

Additional Notes