



## Armour Pharmaceutical Company Limited

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Our Ref RGE/KJ

19th October, 1979.

The Medical Assessor,  
Committee on Safety of Medicines,  
Finsbury Square House,  
33/37A Finsbury Square,  
London,  
EC2A 1PP.

Dear Sir,

Factorate Batch S23409

Please find enclosed one Yellow Form concerning a case of jaundice following the use of Factorate batch S23409 and NHS Factor VIII. This is the only report we have received that has been associated with this batch.

The case was reported by Professor Ingram of St Thomas' Hospital, London. If any further details are received we will, of course, immediately send them on to you.

Yours faithfully,

GRO-C

R. G. Butchart, B Pharm MPS  
Clinical Research Officer

Enc.

Mr. K. W. Fitch  
Dr. W. S. Munro  
Mr. P. B. Lloyd  
Mr. E. R. James  
Mr. C. R. Bishop  
Miss P. A. Goldsmith  
Mr. B. Beesley  
Mr. D. Ferguson

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IN CONFIDENCE

CSMAR IND  
B.M272 030

## REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

## NOTES FOR GUIDANCE

300300

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)

From (Name and address):  
Company doctor or other representative of product  
licence holder—

Dr. W. S. Munro  
Armour Pharmaceutical Co Ltd,  
Hampton Park, Eastbourne, Sussex.

Signed: **GRO-C** Date: 16th Oct 79

Sex M	Age or Date of Birth 21	Weight if known 83 kg	Name of patient's own doctor (and address if known): Professor G. I. C. Ingram, Dept of Haematology, Louis Jenner Laboratories, St. Thomas' Hospital & Medical School, London.
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DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTORATE Batch S23409	IV	248 iu	31/3/79		Treatment for a fall
NHS FACTOR VIII	IV	680 iu	31/3/79		(Von Willebrand's patient)
(*For Vaccines give Batch No.)					
P ACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
Jaundice and malaise. Raised LFTs:			25/4/79		
Bilirubin 169 $\mu$ mol/l, SGOT 2180 iu/l, Alk					
Phos 20 KA units, HBsAg negative, HBsAb positive			3/4/79		Present condition
HBsAg negative HBsAb positive			1/5/79		Satisfactory (8/10/79)

Additional Notes