



# Armour Pharmaceutical Company Limited

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Our Ref RGB/KJ

19th June, 1979.

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

Dear Sir,

Re: Factorate Batch S18406.

Please find enclosed one Yellow Form reporting a case of hepatitis suspected of being associated with the administration of Factorate batch S18406. This is the only report we have received with this batch.

The case was reported by Dr. Kernoff at the Haemophilia Centre, The Royal Free Hospital, Hampstead. If any further details are received, we will immediately pass them on.

Yours faithfully,

GRO-C

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

Enc.

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

300310

## 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)

From (Name and address):

Company doctor or other representative of product  
licence holder—

DR. W. S. MUNRO  
ARMOUR PHARMACEUTICAL CO LTD  
HAMPTON PARK, EASTBOURNE

Signed: **GRO-C**

Date: 19/6/79

Sex

Age or Date  
of Birth  
56

Weight  
if known  
73.6 Kg

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

DR. P.B.A. KERNOFF  
CO-DIRECTOR HAEMOPHILIA CENTRE  
THE ROYAL FREE HOSPITAL  
LONDON NW3 2QG

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTOR VIII					
FACTORATE					
BATCH S18406	I.V.	1-2 units	5/5/79		)
					)
PROFILATE					)
BATCH A10390	I.V.	727 units X 4	8/5/79	13/5/79	) HAEMOPHILIA A
					)
(*For Vaccines give Batch No.)					

REACTIONS (List separately)

Started

Ended

OUTCOME (e.g. fatal; recovered)

HEPATITIS: Patient jaundiced

About

Patient still jaundiced

Raised LFT's (i.e. raised AST)

26/5/79

and under observation in  
hospital

Multiple sequential tests for HBs Ag

all negative.

Additional Notes

General Malaise, other-wise reasonably well and no complications to date.