

Adv. reach. - Factorate 30/79
300305



Armour Pharmaceutical Company Limited

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Our Ref. PAG/EW

10 September 1979

The Medical Assessor,
Com. Safety Med.,
Finsbury Square House,
33/37A Finsbury Square,
London, EC2A 1PP.

Dear Sir,

Re: Factorate

Please find enclosed a Yellow Form concerning a case of hepatitis following the use of several batches of Factorate.

Along with the three reports sent to you on 20th August, Batch S17405 is the common denominator. The patient, however, was HBs antigen negative before and after treatment.

Immediately we receive the results of Dr. Dane's retesting of this batch we will contact you again.

Yours faithfully,

GRO-C

Pauline A. Goldsmith, B.S., Dip. Inf. Sci.,
Medical Services Manager

Enc.

c.c. Mr R G Butchart

ARMOUR000499

ARMO0000040_0001

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

300305

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.

Hampden Park, Eastbourne, East Sussex.

Signed:

GRO-C

Date:

12/9/79

Sex

Age or Date
of BirthWeight
if known

30.5 Kg.

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

MR. J. H. MATTHEWS

SENIOR REGISTRAR OF HAEMATOLOGY

THE LEICESTER ROYAL INFIRMARY

LEICESTER

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
Factorate Batch S18406	I M		28/12/78	26/6/79	Haemophilia
" " S17005					
" " S17405					
" " S20107					
" " S26411					
Lister Institute	I M		13/6/79		"
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
Hepatitis			1st Week		Recovered
			in July		

Additional Notes HBs Ag status negative before and after treatment.