

Our ref: RGB/SAB

21st February, 1979

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

Dear Sir,

Factorate

Please find enclosed five Yellow Forms reporting five cases of hepatitis with Factorate.

The five cases have been reported from two centres, but only one batch of Factorate - batch S12303 - has been implicated more than once.

Dr. Reporting Reaction	Haemophilia Centre	Batch Number of Factorate
Dr. J. Keith Wood	Leicester Royal Infirmary	S12303
Dr. J. Keith Wood	Leicester Royal Infirmary	S12303
Dr. P. J. Green	Royal Victoria Hospital, Boscombe,	R7011
"	Bournemouth	R7111
"		R8612

These are the only reports that we have received for these particular batches, if any further details are received concerning these cases, we will of course, immediately send them on to you.

Yours faithfully,

Mr. R. G. Butchart, B. Pharm., M.P.S.
Clinical Research Officer

Encs.

c.c. Mr. K. W. Fitch
Dr. W. S. Muhro
Mr. D. Ferguson

ARMOUR000459

ARMO0000029_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

300312

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. WM. SIM. MUNRO,
ARMOUR PHARMACEUTICAL COMPANY, LTD.,
HAMPDEN PARK,
EASTBOURNE, EAST SUSSEX.

Signed: **GRO-C** Date: 21/2/79

Sex

MALE

Age or Date
of BirthWeight
if known

NOT KNOWN

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

DR. J. KEITH WOOD,
CONSULTANT HAEMATOLOGIST,
LEICESTER ROYAL INFIRMARY,
LEICESTER.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTOR VIII					
FACTORATE BATCH S12303	I.V.	11 VIALS IN ALL	1.12.78	6.12.78	HAEMOPHILIA A
LISTER INSTITUTE FACTOR VIII BATCH HL 1462	I.V.	4 VIALS	ON	6.12.78	HAEMOPHILIA A
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal; recovered)
DEVELOPED CLINICAL HEPATITIS			22.12.78		
LIVER FUNCTION TESTS INDICATE CONTINUING HEPATITIS (FEB 1979)					

Additional Notes

PATIENT IS PRESENTLY SATISFACTORY, REMAINS SLIGHTLY JAUNDICED, BUT WELL (6.2.79)

HB Ag NEGATIVE ON 2.12.78

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

300313

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. WM. SIM. MUNRO,
ARMOUR PHARMACEUTICAL COMPANY LTD.,
HAMPDEN PARK, EASTBOURNE,
EAST SUSSEX. 1 1

Signed:

GRO-C

Date: 21/1/79

Sex

MALE

Age or Date
of BirthWeight
if known

NOT KNOWN

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

DR. J. KEITH WOOD,
CONSULTANT HAEMATOLOGIST,
LEICESTER ROYAL INFIRMARY,
LEICESTER.DRUGS* (Brand name where
appropriate)

ROUTE

DOSE

DATES

From

To

INDICATIONS

FACTOR VIII

FACTORATE BATCH S12303

IV

2 VIALS

21.11.78

HAEMOPHILIA A

(*For Vaccines give Batch No.)

REACTIONS (List separately)

Started

Ended

OUTCOME (e.g. fatal; recovered)

BECAME JAUNDICED

20.12.78

LIVER FUNCTION TESTS CONSISTENT WITH

HEPATITIS THROUGHOUT

Additional Notes

HB Ag NEGATIVE ON 20.12.78

PATIENT SATISFACTORY 8.2.79

DM 32427 Sm 1973 G. R & S. Ltd. Gp 3613

ARMOUR000461

ARMO0000029_0003

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

300314

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. WM. SIM. MUNRO
ARMOUR PHARMACEUTICAL COMPANY LTD
HAMPDEN PARK,
EASTBOURNE EAST SUSSEX
Signed: **GRO-C** Date: 21/2/79

Sex
MALE

Age or Date
of Birth 67

Weight
if known
UNKNOWN

Name of patient's own doctor (and address if known):
DR. P. J. GREEN,
CONSULTANT HAEMATOLOGIST,
ROYAL VICTORIA HOSPITAL,
BOURNEMOUTH.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTOR VIII					
FACTORATE BATCH R7011	I.V.	12	24/8/78	7/9/78	BLEEDING PROSTATECTOMY
		BOTTLES			
		X 276			
		I.U.			
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal; recovered)
BECAME JAUNDICED					
LIVER FUNCTION TESTS VERY ABNORMAL			1/11/78	MID	PATIENT NOW COMPLETELY FIT
HE Ag NEGATIVE BEFORE THIS TREATMENT				DECEMBER	
AND ALSO NEGATIVE ON 13/11/78					

Additional Notes

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

300315

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. WM. SIM. MUNRO,
ARMOUR PHARMACEUTICAL COMPANY LTD.,
EASTBOURNE, EAST SUSSEX.

Signed: **GRO-C**

Date: 21/2/79

Sex

MALE

Age or Date
of Birth

36

Weight
if known

UNKNOWN

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

DR. P. J. GREEN,
CONSULTANT HAEMATOLOGIST,
ROYAL VICTORIA HOSPITAL,
BOURNEMOUTH

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTOR VIII					
FACTORATE BATCH R8612	I.V.	7	9/1/79	15/1/79	HERNIA OPERATION IN
(DOUBLE FILL)		BOTTLES			HAEMOPHILIAC PATIENT
		X 632			
		I.U.			
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal; recovered)
BECAME JAUNDICED			9/2/79		
RAISED LIVER FUNCTION TESTS					

Additional Notes

HB Ag NEGATIVE ON 9/2/79

PATIENT STILL JAUNDICED BUT RECOVERING (15/2/79)

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

300316

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. WM. SIM. MUNRO,
ARMOUR PHARMACEUTICAL COMPANY LTD.,
HAMPTON PARK,
EASTBOURNE, EAST SUSSEX.

Signed: **GRO-C**

Date: 4/1/79.

Sex
MALE

Age or Date
of Birth
75

Weight
if known
UNKNOWN

Name of patient's own doctor (and address if known):
DR. P. J. GREEN,
CONSULTANT HAEMATOLOGIST,
ROYAL VICTORIA HOSPITAL,
BOURNEMOUTH.

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTOR VIII					
FACTORATE BATCH R7111	I.V.	3 BOTTLES X 273	ON	30/10/78	BLEEDING AFTER TOOTH EXTRACTION
		I.U.			
NBS FACTOR VIII	I.V.	500 I.U.	ON	30/10/78	BLEEDING AFTER TOOTH EXTRACTION
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
BECAME JAUNDICED			27/12/78	16/1/79	PATIENT NOW COMPLETELY FIT
VERY ABNORMAL LIVER FUNCTION TESTS					
HB Ag NEGATIVE ON 5/1/79					

Additional Notes