

IN CA CE

A-41 P-2 G-2-79

CSM/AR/IND
B/M272.086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

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.

073764

Name of Patient:
(Required in confidence to
allow linkage with other
reports for same patient)

GRO-B

From (Name and address):

Company doctor or other representative of product

licence holder—

GRO-B

Armour Pharmaceutical Co. Ltd.,

Hampden

East

Signed:

GRO-B

Date: 1/2/79

Sex

Age or Date
of BirthWeight
if known

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

GRO-B

Co. Director, Haemophilia Centre,
The Royal Free Hospital,
London.

MALE

GRO-C/50

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
CRYOPRECIPITATE	1/v	approx. 25, 350 units	1/7/78	15/12/78	HAEMOPHILIC BLEEDS
ARMOUR FACTOR VIII (FACTORATE batch S9801)	1/v	1, 320 units	20/12/78	5/1/79	HAEMOPHILIC BLEEDS
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
Jaundice, anorexia, nausea, vomiting,			approx.		
discoloured urine and raised LFT's			7/1/79		

Additional Notes

Found to be HB_s Ag negative in January 1979

GRO-B

reported that

GRO-B

is considered to have non A

non B Hepatitis.

IN IDENCE

Add on 8.3.79.

CSM/AR/IND
B/M272 086

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GRO-B

From (Name and address):

Company doctor or other representative of product

licence holder—

GRO-B

ARMOUR PHARM

HAMPO

EAST

Signed:

GRO-B

SEX.

Date: 21/2/79.

Sex

MALE

Age or Date
of Birth

GRO-C, 50

Weight

if known

NOT KNOWN

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

GRO-B

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

Copy to:

GRO-B

P.L. 15.5.79.

H.S.S. POST-TRANSFUSION HEPATITIS

Report of Case

079001

D.O.B. 12/12/48

1. Name GRO-B 12
2. Hospital R.V.H. Bournemouth Consultant GRO-B
3. Home Address of Patient
4. Transfused on 11.3.79 19.. at R.V.H.
5. Jaundice First Noticed on 23/3/79 19.. Incubation period approx 10 days
6. Outcome of Hepatitis: Recovery/Death If fatal, date of death19..
7. Transfusion Fluids Used:

Blood containers			Dried Plasmabottles		
Au			Au		
Bottle Nos.	A/G	A/B	Batch Nos.	A/G	A/B
<u>HL 1527 x 4</u>					
<u>ie 1080v factor</u>					
<u>VIII</u>					

8. Brief Clinical Notes: (including, if possible, conditions necessitating transfusion)
The diagnosis of haemophilia in this child is not certain and while awaiting an appointment at Oxford for investigation he had a tooth pulled and released pathogen because of severe bleeding from socket
9. Test for Au antigen/antibody on patient: Negative
10. Post-mortem: Yes/No. If yes, give relevant particulars
11. Remarks: eg. Your opinion on validity of diagnosis of serum hepatitis
Incubation time a little on short side but may be Non A Non B hepatitis - No history of contact with other jaundiced person.

Signed ...

GRO-B

Regional Transfusion Director, Region

Date

CONFIDENCE

Ack JM 9/7/79

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078500

Name of Patient:
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allow linkage with other
reports for same patient)

GRO-B

From (Name and address):

Company doctor or other representative of product

GRO-B

ARMOUR PHARMACEUTICAL CO LTD

HAMP

GRO-B

BOURNE

Signed:

Date: 19/6/79

Sex

M

Age or Date
of Birth
56Weight
if known
73.6 Kg

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

GRO-B

LUP-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 vials	5/5/79)
)
PROFILATE)
BATCH A10390	I.V.	727 units	8/5/79	13/5/79) HAEMOPHILIA A
		X 4)
(*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
Multiple sequential tests for HBs Ag					hospital
all negative.					

Additional Notes

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

CONFIDENCE

Ack JM 13/10/79.

CSM/AR/IND
B/M272,086

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GRO-B

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

ARMOUR PHARMACEUTICAL CO LTD

HAMPDEN

EASTBO

Signed:

GRO-B

Date: 25/7/79.

Sex

Age or Date
of BirthWeight
if known

M

50

Name of doctor (and address if known):

GRO-B

DEPT OF HAEMATOLOGY
HALLAMSHIRE HOSPITAL
SHEFFIELD

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
Factorate		230-250			
BATCH S23209	iv	units	25/5/79	2/6/79	Haemarthrosis
		27 bottles			
OTHER COMMERCIAL FACTOR	iv		15/1/79	20/1/79	
VIII					
NHS FACTOR VIII	iv		17/2/79	23/5/79	
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
HEPATITIS			2/6/79		
RAISED LIVER FUNCTION TESTS 5/6/79					
BECAME HBAg POSITIVE 2/6/79					

Additional Note:

10/7/79

GRO-B

reported the following to us:
"still has hepatitis. The time interval between giving Factorate and
developing hepatitis does seem too short for the Factorate to have been
the causative agent".

IN CONFIDENCE

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

CSM AR IND
B/M272.086

ack'd
sent 10/9/79
080491

NOTES FOR GUIDANCE

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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 GRO-B Amour Pharmaceuticals Co Ltd Hampton Signed: GRO-B sex date: 14th August	
Sex M	Age or Date of Birth	Weight if known	Name of patient's own doctor (and address if known): GRO-B Consultant Haematologist, The Leicester Royal Infirmary, Leicester.	

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTORATE					
Batches S12303	iv				
S17405			17/11/78	1/5/79	HAEMOPHILIA A
S18406					
S20107					
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
HEPATITIS					
HBsAg negative on 10/1/79					
became HBsAg positive on 8/5/79					

Additional Notes

Received Factorate as home treatment

IN CONFIDENCE

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

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CSM/AR/IND
B/M272/086

ackd 10/9/79

080489

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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		
			GRO-B Armour Pharmaceutical Co Ltd, Hampden Park, Eastbourne, Sussex.		
			Signed: GRO-B Date: 17th August		
Sex	Age or Date of Birth	Weight if known	Name of patient's own doctor (and address if known):		
			GRO-B St. James's University Hospital, Beckett Street, LEEDS.		

DRUGS* (Brand name where appropriate)	ROUTE	DOSE	DATES		INDICATIONS
			From	To	
FACTORATE	iv	100mg	March	1979	HAEMOPHILIA A
Batch S17405	iv		January	1979	
Batch S16005	iv		January	1979	
ANOTHER FACTOR VIII	iv		January	1979	
Preparation	iv		January	1979	
(*For Vaccines give Batch No.)					
REACTIONS (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)
HBsAg positive Hepatitis					

Additional Notes

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GRO-B

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

GRO-B

Signed:

GRO-B

Ltd. East Sussex
Date: 12/9

Sex

Age or Date
of Birth

M

GRO-C 1968

Weight
if known

30.5 Kg.

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

GRO-B

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.