IN Co CE 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. 073764 4. Please do not be deterred from reporting because some details are not known.

Name of Patient: (Required in con allow linkage wit reports for same	-В	Compa licence	GRO-B					
Sex MALE	of Birth if known			Name of patient's own doctor (and address if known): GRO-B Co. Director, Haemophilia Centre, The Royal Free Hospital, London.				
DRUGS* (Brand	d name where appropriate)	ROUTE	DOSE	From	TES To	INDICATIONS		
ARMOUR FACT		1/v	epprox. 25, 350 units 1, 320 units	20/12/78	15/12/78	HAEMOPHILIC BLEEDS HAEMOPHILIC BLEEDS		
(*For Vaccines g			0 0 1 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	Started	Ended	OUTCOME (e.g. fatal: recovered)		
Jaundice,	anorexia, nausea	, vomiting	,	approx.				
discoloure	d urine and rais	ed LFT's		7/1/79				

GRO-B reported that GRO-B is considered to have non A non B Hepatitis.

Dd 224427 5m 1/73 G. B & S. Ltd. Gp 3613

IN IDENCE

CSM/AR, IND B/M272, 086

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4	Please do r	of be	acterrea	from	reporting	because	some	details	are not	KNOWN.

MYGGRU

Name of Patient: (Required in confidence to allow linkage with other reports for same patient) GRO-B					e holder— IUR PHARM/ D	ess): other representative of product GRO-B SEX. Date: 21/2/79.				
Sex MALE	of Birth if known				Name of national course doctor (and address if known): GRO-B CONSULTANT HAEMATOLOGIST, LEICESTER ROYAL INFIRMARY, LEICESTER.					
DRUGS* (Brai	nd name where appropriate)	ROUTE	DOSE	DATES From To		INDICATIONS				
System by 184 by great contents ###################################	E BATCH S12303	1.v.	11 VIALS IN ALL		6.12.78	HAEMOPHILIA A				
VIII BA	TCH HL 1452 give Batch No.) (List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)				
DEVELOPE	D CLINICAL HEPATI NCTION TESTS INDIC S (FEB 1979)	n a se dia Constitue amazamente de encio Indone Constitue a dia Constitue de Consti	NUING	22.12.78	department of the control of the con	COTOCH (cg. mar. teoreta)				

Additional Notes

PATIENT IS PRESENTLY SATISFACTORY, REMAINS SLIGHTLY JAUNDICED, BUT WELL (8.2.79)
HB Ag NEGATIVE ON 2.12.78

Dd 224427 5st 1/73 G. B & S. Ltd. Gp 3613

GRO-B	15.5.79. OST-TRANSFUSION HYPATI	TIS 9/105	(12/12/43
,	Report of Case	0790	
1. Name GRO-B 2. Hospital KVH 8946	ombl Consult	GRO-	}
2 St. A. 2 Sunna D. A. d. and			
4. Transfused on	19 19 04	RVH.	
5. Jaundice First Noticed on	23/3/79 10 7	nouhation period a	Mox 10 days
6. Outcome of Hepatitis: Rec	covery/Death II Is	tal, date of death	************
7. Transfusion Fluids Used:		f	N-443
Blood		Dried Flasma	
Bottle Bot	Au tle	Batch	Au
Nos. AG AB Nos	A/G A/B	Nos.	A∕c A∕B
77 77 37 19 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	· · · · · · · · · · · · · · · · · · ·	***********	*****
HL 1527 × 4	******	••••••	*****
ic. 1080 v. Fuctor		***********	*****
Vul	******	• • • • • • • • • • • • • • • • • • • •	*****
		***********	*****
, ********* **** .*** .***	******	**********	*****
for iverfigation he have and for for Au antigen/antib 10. Post-mortem: Yes/No. 11. Romarka: eg. Your opin Thanbalian time Non A Non B hap	I here phila the arrenting an had a footh were following ody on patient: If yes, give relevant ion on validity of die here a lette an smad alte - No moto	appointment and red from Scietal Negalive particulars coosis of scrumber site out w	en a faction
dir jamoned pa		Signed	GRO-B
Ros	ional Transfusion Dire		A A
•		Date	7.7

CONFIDENCE

ACK JM 9/4/49.

CSM/AR/IND B/M272/086

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

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- 4. Please do not be deterred from reporting because some details are not known.

Name of Patier (Required in co allow linkage w reports for sam	onfidence to	RO-B	,	From (Name and address): Company doctor or other representative of product GRO-B ARMOLIA BUADMAGELITEGAL CO LTD HAMF Signed: GRO-B Date: 19/6/79					
Sex M	Age or Date of Birth 56	Weight if know 73.6	-	THE R	Name of nation's own doctor (and address if known): GRO-B UU-UIRECTUR HAEHUPHILIA CENTRE THE ROYAL FREE HOSPITAL LONDON NW3 2QG				
DRUGS* (Bra	nd name where	ROUTE	DOSE	DA	TES	INDICATIONS			
	appropriate)			From	То				
FACTOR.	VIII			,					
FACTOR					*******************				
444	BATCH S18406		I.V. 1-2 vis 5/5/79))				
*******************	COMMON TO BE EAST OF THE COMPANY OF THE COMPANY COMPANY COMPANY		***************************************	*****************	**************)			
PROFILA	TE			**************	**********************)			
BATCH A	10390	ı.v.	727units	1) HAEMOPHILIA A			
PROPERTY AND PROPERTY OF PROPE	1 i	*************	X 4	*****************	************************)			
Respondent bill bed Appear to it is	*		*************	APRALINA PARIS PROPERTY OF THE PARIS	*****************	**************************************			
******************	eccumumumanah mebunuh mebunuh finakai di semani	145.1		****************	*******************				
(*For Vaccines	give Batch No.)	nicht a indværer rommen m	10 (eccinistrations)	******************	es i de nice con derá a a celina e age	entektopa Stårnå kilvikom sa åregna årikator og en neger en priss za ana kan blev i stars a			
REACTIONS (List separately)				Started	Ended	OUTCOME (e.g. fatal: recovered)			
HEPATIT	HEPATITIS: Patient jaundiced				·	Patient still jaundiced			
Raised	LFT's (i.e. ra	ided AST		26/5/7	9 -	and under observation in			
	Multiple sequential tests for HBs Ag					hospital			
all neg	ative.				***************************************	eminione i in in international in international despetation in the internation is a second contract of the internation in the internation in the internation is a second in the internation in the internat			

Additional Notes

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

Dd 224427 5m 1/73 G. B & S. Lul. Gp 3613

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CSM/AR/IND B/M272/086

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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— ARMOUR PHARMACEUTICAL CO LTD HAMPDET EASTBO Signed: GRO-B Date: 25/1/79,				
Sex M	of Birth if known			GRO-B DEPT OF HAEMATOLOGY HALLAMSHIRE HOSPITAL SHEPFIELD				
DRUGS* (Bran		ROUTE	DOSE		TES	INDICATIONS		
	appropriate)			From	То			

FACTORAS	TE		230-250		*****************	·		
BATCH S2	23209	iv	units	25/5/79	2/6//9	Haemarthrosis		
gy pyjedian a i komondana s ir ki dra ir kil	 		x7botts	**************	addh dal lett i in i in eigilbean			
OTHER CO	OMMERCIAL FACTOR		# 870 8 10 11 10 11 11 11 11 11 11 11 11 11 11	12/1/13	20/1//9			
NHS FACT (*For Vaccines	TOR VIII give Batch No.)	iv		17/2/79	26/5/79			
REACTIONS	(List separately)			Started	Ended	OUTCOME (e.g. fatal: recovered)		
5012025244444444444444444444444444444444	IS LIVER FUNCTION TEST BAG POSITIVE 2/6/2		**************************************	2/6/79	Villa võekkoluballatajap, I Kandonahanan kolubordean			
78038048748890847444844					44 M			

dditional	Note	<u></u>	•
			•

GRO-B reported the following to us:
"STILL has hepatitis. The time interval between giving Factorate and developing nepatitis aces seem too short for the Factorate to have been the causative agent".

Dd 224127 5m 1/73 G. B & S. Ltd. Gp 3613

IN CONFIDENCE

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES OF 19/79

080491

CSM/AR/IND B/M272/086

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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 Phatmacauttaal Co. Ltd.					
	GRO-B					RO-B			
Sex Age or Date of Birth Weight if known				The Le	Name of nation's own doctor (and address if known): GRO-B Consortent resemble togist, The Leicester Royal Infirmary, Leicester.				
DRUGS* (Bran		ROUTE	DOSE		TES	INDICATIONS			
MATERIAL PROPERTY OF THE PROPE	appropriate)		errore and a construction	From	То				
Batch (*For Vaccines §	S17405 (S18406 S20107 S20107	i.v		.17/11/7	3.1/5/79	HAEMOPHILIA A			
REACTIONS (List separately)		Who decared to value	Started	Ended	OUTCOME (e.g. fatal: recovered)			
_	ITIS negative on 10/1 e HBsAg positive				# # # # # # # # # # # # # # # # # # #				

Additional Notes

Received Factorate as home treatment

Dd 224127 5st 1/73 G. B & S. Ltd. Gp 3613

IN CONFIDENCE

REPORT ON SUSPECTED TOXICITY OR SIDE-EFFECTS

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

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RECORD TOXICITY OR SIDE-EFFECTS

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Name of Patient (Required in con allow linkage wit reports for same	fidence to h other	The state of the s	on the	Comp	RO-B	other representative of product
		Vi.	Hampde Signed:		stbourha Sussex. RO-B Date: 17th August	
porrs in same : Sex	Weight if known	project 4 Sampling	Manne of continual annual decree (and address if known): GRO-B St. James's University Hospital, Beckett Street, LEEDS.			
TD1100+ /D	4	ROUTE	DOSE	D/	TES	T notations
DRUGS* (Bran	appropriate)	ROUIE	DOSE	From	То	INDICATIONS
	*				1964	
FACTORATE .		2	post :		For March	HAEMOPHILIA A
Batch S1740	ALLEGE PROPERTY OF THE PARTY OF	1		March	1979	
Batch S1600		iv		Januaru	1979	
**************************************			*		***************************************	***************************************
ANOTHER RAC	TOR VIII	*****		***************************************	*******************	***************************************
				T	1979	
ereparation		1		vanueury		**************************************
					************************	***************************************
*For Vaccines g	ive Batch No.)		*********	*************	*****************	**************************************
REACTIONS (List separately)	1		Started	Ended	OUTCOME (e.g. fatal: recovered)
	:					
HRsAa posit	ive Hepatitis		************	***************	*************	en na vana pare en na na na na na neverna vana na
	10	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	e gar eaf	2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 - 2 -	emeca seriana maneda i in	**************************************
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Dd 224427 5m 1/73 G. B & S. Ltd. Gp 3613

Additional Notes

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CSM/AR/IND B/M272/086

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Name of Patient: (Required in confidence allow linkage with other reports for same patient	e (in)	From (Name and address): Company doctor or other representative of product licence holder GRO-B						
GRO-B					GR	О-В	Ltd. East Sussex. Date: 12/9/19	
	ge or Date f Birth	Weight if known		Name of patient's own doctor (and address if known): GRO-B SENIOR REGISTRAR OF HAEMATOLOGY				
M GR	_{0-c} 1968	30.5 Kg		LEICES	TER	DYAL INFIRMARY		
DRUGS* (Brand name	where	ROUTE	DOSE	DA	TES	n	NDICATIONS	
	priate)			From .	To	(N.)		
Factorate Batch S	18406	I M		28/12/7	26/6/79	Haemoph	ilia 🥳	
" " S	17005			1				
	17405					*************		
и и с	20107					******************		
******************************	26411		*************	************	***************************************	*************		
**************************************	**********************	*	**********	***************************************	***********	*******************		
Lister Institut	e	I M		13/6/79		#1 ·		
***************************************				***************************************	************	***************		
d - m d - m	(444)**********************************	***************************************	************		**********************	******************	*************	
*For Vaccines give Bat	ch No.)	**************************************	***********	****************	************************	***********		
REACTIONS (List sep	arately)			Started	Ended	OUTCOM	tE (e.g. fatal: recovered)	
Hepatitis	* * `:			lst Week		Recover	ed	
*	***************************************	-		in July	*	*******************	######################################	
\$4.64.4.6.03.666.00.002.00.00.00.00.00.00.00.00.00.00.00	**************************	*************	**********	1		***************	***************************************	

Additional Notes HBs Ag status negative before and after treatment.

Dd 224427 5m 1/73 G. B & S. Lul. Gp 3613