



# Armour Pharmaceutical Company Limited

Hamnden Park, Eastbourne, East Sussex BN22 9AG. Registered in England (No. 1481111)  
Office, tel. Eastbourne (0323) 73442 telex 871411 Armphb Eastbourne  
Plant, tel. Eastbourne (0323) 51111 telex 877411 Labarm telegrams and cables: Armphab Eastbourne

Our Ref RGB/KJ

21st September, 1979.

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

Dear Sir,

Re: Factorate

Please find enclosed one Yellow Form concerning a report of hepatitis following the use of two batches of Factorate.

Along with the four reports sent to you on 20th August and 10th September, batch S17405 is a common denominator. This patient was, however, HBS antigen negative before and after treatment.

Further to our previous correspondence about this batch, I can now inform you that batch S17405 has since been re-tested for hepatitis B antigen, by Dr Dane at the Middlesex Hospital, with negative results.

I would be grateful if you could add this information to that given on the forms.

Yours faithfully,

**GRO-C**

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

Enc.

ARMOUR000503

ARMO0000042\_0001

CSM/AR IND  
B/M272:086

For the information of THE COMMITTEE ON SAFETY OF MEDICINES

300304

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) UNKNOWN			From (Name and address): Company doctor or other representative of product licence holder— Dr. W. S. Munro, Armour Pharmaceutical Co Ltd, Hampden Park, Eastbourne Sussex. Signed: <b>GRO-C</b> Date: 21st September			
Sex	Age or Date of Birth	Weight if known	Name of patient's own doctor (and address if known): DR. T. E. BLECHER, CONSULTANT HAEMATOLOGIST, DEPT OF HAEMATOLOGY, UNIVERSITY HOSPITAL, NOTTINGHAM.			
M	66	68.5				
DRUGS* (Brand name where appropriate)		ROUTE	DOSE	DATES		INDICATIONS
				From	To	
FACTORATE Batch S17405		IV	504 i.u.	20/4/79		Cover for hernia operation
FACTORATE Batch S23509		IV	235 i.u.	20/4/79	STAT	
CRYOPRECIPITATE		IV	32 bags	20/4/79	22/4/79	" " " "
(*For Vaccines give Batch No.)						
REACTIONS (List separately)				Started	Ended	OUTCOME (e.g. fatal: recovered)
Deep Jaundice				26/5/79	25/7/79	
4/6/79 Liver Function Tests Raised: Alk Phos.						
218 i.u./l; Bilirubin 346 $\mu$ mol/l; Alb 34 g/l;						
Ala Am Tr 840 i.u./l; $\gamma$ -Glut Tr 151 i.u./l.						
HBsAg: Not Detected.						

Patient seen 25/7/79: not jaundiced, but still anorexic.