

FOLLOW-UP FORM FOR SUSPECTED ADR AFTER PROCYSBI

Questionnaire for detailed follow-up of encephalopathy

For Office use only

Case Number	
Date received to company:	(dd/mm/yy)

Patient Details :

Patient	Male	☐
	Female	☐
Age at time of event or DOB		
Hosp / ID No:		

Adverse Reaction Description	
Start date	Stop date (dd/mm/yy)

Laboratory Investigations :

Please provide:	Date of test	Date of test	Date of test	Date of test
AST				
ALT				
Alkaline phosphatase				
Calcium				
Electrolytes				
Urea				
Creatinine				
Platelet count				

Has toxicology screen been checked?	☐ Yes ☐ No	If yes when? (dd/mm/yy)
If so what tests and results?		

Has CSF been checked?	☐ Yes ☐ No	If yes when? (dd/mm/yy)
If so what tests and results?		

Other investigations:

Have imaging studies been performed?	☐ Yes ☐ No	If yes when? (dd/mm/yy)
If so what tests and results?		

Has EEG been performed?	☐ Yes ☐ No	If yes when? (dd/mm/yy)
If so what tests and results?		

Past Medical History :

Is there a medical history of	☐ Underlying liver or biliary tract disease	☐ Excessive alcohol consumption
☐ Fasting, malnutrition, obesity	☐ Recent hypotension or congestive heart failure	☐ Respiratory failure
☐ Renal disease? if yes what degree of impairment		

Clinical Exam :

Were there any neurological manifestations?			
Muscle stiffness/spasms	☐ Yes ☐ No	Nystagmus	☐ Yes ☐ No
		Tremor	☐ Yes ☐ No

Additional Information :

Please provide more information in box below if you answered Yes to any of these questions

Reporting ☐ doctor ☐ pharmacist ☐ other:	Contact details (email or phone)	
Name:		
Address:		
Postcode:	Signature	Date: (dd/mm/yy)