

GE HealthCare Pharmaceutical Diagnostics Adverse Event Intake Form

Please complete this form with all known details and send to gpv.drugsafety@gehealthcare.com

Receipt Date (Date anyone representing GEHC was made aware of the AE) DD-MMM-YYYY

Local Case Number (to be completed by the Local Safety Unit (PV Team) only)

Local Safety Unit - Territory/Company Name

PART 1: REPORTER DETAILS

Reporters Name	Telephone	Email
Institution Name	City/ State	Country

Reporter Type: Healthcare Professional Consumer Other (please specify):

PART 2: PATIENT INFORMATION

Patient Initials <i>(First name initial -Last name initial)</i>	Gender	Pregnant	Weight	Height	Date of Birth DD-MMM-YYYY	Age <i>(years)</i>	Age Group <i>(if age unknown)</i>
		Yes No	kg lb	cm in			

PART 3: ADVERSE EVENT /PRODUCT COMPLAINT INFORMATION

Adverse Event (AE): <i>(If space insufficient in this section, additional AEs can be described in Part 5)</i>	AE start date DD-MMM-YYYY	AE stop date DD-MMM-YYYY	Latency <i>How long after start of drug administration did symptoms begin?</i>	Duration <i>How long did symptoms last? (or indicate if still ongoing)</i>	Event Outcome <i>(If left empty, outcome will be considered unknown)</i>	Seriousness Criteria - provide AE seriousness by selecting most appropriate criterion: <ul style="list-style-type: none"> • Non-serious - or - • Serious - please specify from criterion: Death; Life-threatening; Hospitalization; Disability; Other Medically significant
					Not Recovered Recovering Recovered	
					Not Recovered Recovering Recovered	
					Not Recovered Recovering Recovered	

PART 4: SUSPECT DRUG INFORMATION

Suspect Product Info <i>(Trade or Generic Name)</i>	Route and Formulation	Batch/Lot No.	Dose (Units) & Frequency	Drug start date DD-MMM-YYYY	Duration of drug administration	Exam Type/ Procedure and Indication for procedure <i>(if known)</i>

PART 5: ADDITIONAL INFORMATION REGARDING ADVERSE EVENTS (relevant diagnostic tests, medication patient was taking up to the AE/s, medication taken for treatment of AE/s)

Please provide event and clinical course details, including diagnosis (if known), symptoms, vital signs/ test results. Please document any medications taken in the two weeks preceding the adverse event, as well as any medication taken for treatment of the adverse event. If the patient has died, please provide the cause of death and autopsy details.

PART 6: MEDICAL CONDITIONS / HISTORY

Ongoing
Ongoing
Ongoing
Ongoing

PART 7: SPECIFIED RISK FACTORS

Renal Impairment	Yes	No	Unknown
Asthma	Yes	No	Unknown
Dehydration	Yes	No	Unknown
Allergies	Yes	No	Unknown

PART 8: PREVIOUS CONTRAST EXPOSURE

Has the patient received contrast before?
Yes No Unknown

If yes, did the patient have a reaction to that contrast? **Yes No Unknown** *If yes, specify contrast:*

NAME	SIGNATURE	DATE (DD-MMM-YYYY)

Reporter agrees to be contacted for follow-up if further information is required: Yes No