

TITLE: AE/ADR REPORTING FORM

	Date received:	
SUSPECT DRUG INFORMATION: Product:		
Indication for use:		
Dosage:		
Route: Lot #: Exp		
Start Date (dd/mmm/yyyy): Stop Date	(dd/mmm/yyyy):	
Other (duration): Therapy ended? □Yes	□No □Unknown	
REPORTER INFORMATION Please check the appro	priate check box (V):	
Physician (MD) Specialty: Dentist (DDS/	DMD) Pharmacist Nurse	
□Sales Rep □Consumer □Other:		
Name: First Last name	:	
Address:		
Phone: Fax:		
E-mail:		
PATIENT INFORMATION:		
Sex: Male Female Unknown	Patient Initials:	
Date of Birth (dd/mmm/yyyy): Age: V	Weight: \Box lbs \Box kg	
Pregnant: Yes No Unknown If yes, due date (dd/mmm/yyyy):		
SERIOUS OUTCOME CRITERIA: Please check the a	appropriate check box (V)	
Death	□ Yes □ No □ Unknown	
Life-Threatening	□ Yes □ No □ Unknown	
Hospitalization (required or prolonged)	□ Yes □ No □ Unknown.	
	Specify Dates:	
Disability/Incapacity	□ Yes □ No □ Unknown	
Congenital anomaly	□ Yes □ No □ Unknown	
Other medically significant condition	□ Yes □ No □ Unknown	
	If yes, specify:	
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ADVERSE EVENT INFORMATION:

Event Details:

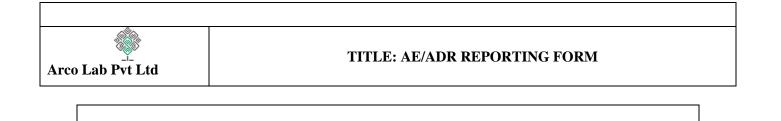
Start Date:	Stop Date:
Suspect drug withdrawn?	\Box Yes \Box No \Box Unknown
Suspected drug dose reduced?	□ Yes □ No □ Unknown
If yes, did the event improve?	\Box Yes \Box No \Box Unknown
Suspected drug reintroduced?	□ Yes □ No □ Unknown
If yes, did the event reoccur?	\Box Yes \Box No \Box Unknown

Note: Please check the appropriate check box (v)

RELEVANT MEDICAL HISTORY: (Including pre-existing medical/surgical conditions) Current Conditions: (Specify dates, if known)

Prior conditions: (Sp	becify dates, if kr	nown)			
Allergies: Yes (Specify:) None Unknown CONCOMITANT MEDICATIONS: (Includes prescription, OTC and herbal/natural products)					
Generic/Trade Name	Indication	Dose/Ro	ute/Frequency	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)

ADVERSE EVENT INFORMATION: (Include relevant tests/laboratory data and any treatment patient received, diagnosis made)



(Attach additional sheet if necessary)

CONSENT TO CONTACT HEALTHCARE PROFESSIONAL (HCP):	□ Yes	🗆 No
CALLER GAVE CONSENT TO PASS DETAILS TO PHARMACOVIGILANCE:	□ Yes	🗆 No

(If yes, name of individual providing consent and date):

Name of individual obtaining consent:

Details of HCP:

Name:	
Profession	
Contact Details:	
Address	
Telephone Number	
Fax/ email	

Prepared by:	
Sign and Date:	

Reviewed by: _____

Sign and Date:	
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