KIVONYX HEALTHCARE

Adverse Event Reporting Form

A. PATIENT DETAILS			
Patient Initials:	**Age:**	**Weight:**	**Country:**
Date of Birth: DD/MM/YYYY	**Sex:** ☐ F ☐ M	**Pregnant:** ☐Yes ☐ No	**Tel No:**

B. ADVERSE EVENT DETAILS	
Date of Event: DD/MM/YYYY	**Date of Report:** DD/MM/YYYY
Description of adverse events: (including sign & Symptoms with specific diagnosis, treatment & action taken)	
Seriousness of Event:	
☐ Death ☐ Initial or Prolonged Hospitalization ☐ Life threatening	☐ Involved persistent or significant disability ☐Congenital anomaly ☐Medically significant & other important condition
Lab test details(with dates, results & normal range)	
Othe relavant history including pre-existing medical conditions (e.g. allergy, pregnancy, smoking & alcohol use, hepatic/renal dysfunction etc)	
Outcome of event:	
☐Recovered ☐ Recovering ☐ Not Recovered ☐ Recovered with sequelae ☐ Fatal ☐ Unknown	

C. DRUG DETAILS			
Name of Drug:	**Dosage:**	**Dose:**	**Indication:**
Route of Admin:	**Strength:**	**Frequency:**	**Exp Date:**
Drug Discontinues? Y/N	**Start Date:** DD/MM/YYYY	**Stop Date:** DD/MM/YYYY	**Batch Number:**
Additional suspect drug(if any) detais as above:			
Concomitant medications (provide with details)			

D. REPORTER DETAILS		
Name:	**Occupation:**	
Address:	Also reported to ☐ Regulatory authority ☐ Distributor ☐ None	
Tel no:		
Email:		
Country:	**Date:** DD/MM/YYYY	**Sign:**

To be filled by Manufacturer	**Send this report to:**
Date received:	KIVONYX HEALTHCARE 403-A, Primate House, Opp. Mother Dairy, Nr. Judges Bunglows, Bodakdev, Ahmedabad-380015, Gujarat, India Phone: +91 79400 64093 Email: drugsafety@kivonyx.com
Name & sign of reciever:	
Internal Assessment No:	

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Advice about Reporting

Report serious adverse events. An event is serious when the patient outcome is

- Death
- Initial or Prolonged Hospitalization
- Life threatening
- Involved persistent or significant disability
- Congenital anomaly
- Medically significant & other important condition

Medical events that may not be immediately life threatening but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed above shall also be considered as serious events.

Report even if

- You are not certain the product caused an adverse reaction
- You don't have all the details

Who can Report

- Any Healthcare professional (Doctors, Dentists, Nurses, Pharmacists, etc)
- Non Healthcare professional (Patient, relative, friend, etc)

How to Report

- Just fill in the sections that apply to your report.
- Attach additional pages if needed
- Use separate form for each patient and event

Where to Report

403-A, Primate House,
Opp. Mother Dairy, Nr. Judges Bunglows,
Bodakdev, Ahmedabad-380015, INDIA
Phone: +91 79400 64093
E-mail: drugsafety@kivonyx.com

Confidentiality

The patient's identity is kept confidential & protected in line with company's policies. The information you provide will be used for the purpose of drug safety surveillance and it may be shared with health authorities. You have the right of access to your personal data which we have.

- Submission of a report does not constitute an admission that medical personnel or manufacturer of the product caused or contributed to the reaction.