Adverse event reporting:

Zydus Pharmacovigilance Philosophy

We at Zydus AH believe that safety is our prime concern ahead of commercial or other interests. All medicines have potential risks as well as benefits. The aim of pharmacovigilance is to protect health by identifying, evaluating and minimizing safety issues in all possible ways.

Drug Safety encompasses all aspects of drug reaction right from side effects/adverse events/adverse drug reactions, lack of efficacy or any undesirable response reported once a medication is administered to the patient.

Adverse event reporting :

We encourage Veterinarians, dairy & poultry farmers and other customers to report any discomfort / adverse events experienced / observed by them after administering or using any Zydus AH product.

To report, you may select any one of the following options:

Please find the adverse event reporting form below, fill and send it to us as per the details given below:

- **Submit the completed form to our company representative**
- **Send the completed form to:**
  Global Pharmacovigilance Department,
  PTC, Cadila Healthcare Limited,
  Div. Zydus AH
  Sarkhej-Bavla N.H.No 8A, Moraiya, Tal: Sanand,
  Ahmedabad – 382210, Gujarat, India.

- **Scan and E-mail the completed form to**: **drugsafety@zyduscadila.com**
  enquiry@zydusahl.com

- **Fax the completed form to**: +91-27176663727 or +91-7926868687

Adverse Event Reporting Form

A. Patient Detail (Animal data)

Species:			Breed/production type:		
Sex		Physiological status:			
□ female	□ male	□ pregnant	□ neutered	□ lactating	□ other
Weight (kilogram):			Age:		
State of health at time of treatment:					
□ good	□ fair	□ poor	□ critical	□ unknown	□ other
Reason(s) for treatment (prevention of what disease(s) or initial diagnosis) :					

B. Adverse Reaction Details

Adverse Reaction Term (s):	Onset Date: Duration of reaction:
Description of adverse events: (including all clinical signs, site of reaction, severity, with specific diagnosis, treatment and action taken):	
Outcome of the Event: ○ **Recovered** ○ **Not Recovered** ○ **Recovered with sequelae** ○ **Fatal** ○ **Unknown**	
Lab test details (Report)	

C. Drug Details

Name of the drug: **Strength:** **Indication:**			
Batch No:		Expiry date:	
Dose and frequency:		Route and site of administration:	
Start date of treatment:	**Stop date:**	Who administered the product: □ veterinarian □ owner □ other	
Use according to label:	□ yes	□ unknown	□ no, explain:
Action taken after reaction:	□ drug withdrawn	□ dose reduced	□ other, explain:
Additional suspect drug (if any), details as above:			
Concomitant medications (provide with details):			

D. Veterinarian (If not the reporter)
Name:
Address: _ **Pin code:** **Tel no.:**
E. Reporter Details

Name:	**Occupation:** [ ] Animal Owner [ ] Pharmacist [ ] Other, specify:……
Address:	**Also reported to:** [ ] Regulatory authority [ ] Distributor [ ] None
Tel No: **Email:**	**Date:** **Signature:**
Send this report to	**To be filled by Manufacturer**
Global Pharmacovigilance Cell, International Regulatory Affairs, (Div. Zydus AH) Zydus Cadila, PTC, Sarkhej-Bavla, N.H.No. 8A, Moraiya, Tal: Sanand, Ahmedabad – 382210, Gujarat Phone: 02717-666594 or 079-26868681 Fax: 02717-6663727 or 079-26868687 Email: drugsafety@zyduscadila.com enquiry@zydusahl.com	Date of received: Name & Sign of receiver Safety report ID Report type: [ ] Initial [ ] Follow up, number: ……

Confidentiality: Customers identity will be held confidential and shall remain protected. Submission of a report does not constitute an admission that veterinary personnel or manufacturer or the product caused or contributed to the event.