EMDOKA

ADVERSE EVENT REPORT FORM		
Please use this form to report adverse events related to our veterinary medicinal products. The form should be filled in as completely as possible and should be sent to us by ordinary letter or by electronic mail. For more information concerning pharmacovigilance, please read the information on our website. Contact details: Emdoka bvba John Lijsenstraat 16 B-2321 Hoogstraten (Belgium) mail@emdoka.be		
IDENTIFICATION	**NAME AND ADDRESS OF SENDER**	**NAME AND ADDRESS/REF. OF PATIENT**
Safety issue in animals ☐ in humans ☐ **Lack of expected efficacy** ☐ **Withdrawal period issues** ☐ **Environmental problems** ☐	Veterinarian ☐ Pharmacist ☐ Owner ☐ Other ☐ Address: Phone: Fax: Mail:	

PATIENT(S) Animal(s) ☐ Human(s) ☐ (for humans fill only age and sex below)

Species	Breed	Sex		Status		Age	Weight	Reason for treatment
		Female Male	☐ ☐	Neutered Pregnant	☐ ☐			

Veterinary medicinal product administered before the suspected adverse reaction (if more products are administered concurrently than the number of boxes available, please mention this in the description of the event below)

	1		2		3	
Name of the veterinary medicinal product						
Pharmaceutical form and strength (ex: 100 mg tablets)						
Marketing authorization number						
Batch number						
Route/site of administration						
Dose/frequency						
Duration of treatment/exposure						
Start date of treatment						
End date of treatment						
Who administered the product? (veterinarian, owner, other,…)						
Do you think that the reaction is due to this product?	Yes No	☐ ☐	Yes No	☐ ☐	Yes No	☐ ☐

Suspected adverse reaction date	
Time between administration and event in minutes, hours or days	
Number treated	
Number reacted	
Number dead	
Duration of the adverse reaction in minutes, hours or days	

Description of the event. Please also indicate if the reaction has been treated, how, with what and what was the result.
Other relevant data (investigations carried out or ongoing, a copy of medical report for human cases,…)
HUMAN CASE If the reported case refers to a human being, please also complete the details of exposure below.

Contact with treated animal Oral ingestion Topical exposure Ocular exposure Injection exposure Other	☐ ☐ ☐ ☐ ☐ ☐	finger	☐	hand	☐	joint	☐	other ☐

Date:	Place:	Name of sender:

By submitting this form to Emdoka bvba you agree that Emdoka bvba will report all data in this form, including personal data, to the competent authorities. Emdoka bvba is legally obliged to keep all the data in its pharmacovigilance database. The data will be shared with other parties only in relation to legal pharmacovigilance duties of Emdoka bvba.