

EU Veterinary Suspected Adverse Reaction Report Form for Veterinarians & Health Professionals

Form to be sent to: Intracare B.V. Voltaweg 4 5466AZ Veghel The Netherlands	IN CONFIDENCE <i>For official use only</i> Ref. Number: <div style="background-color: white; width: 40px; height: 15px; margin: 2px 0;"></div>
Fax: +31 (0)413 362324 Phone: +31 (0)413 354105	
E-mail: cvulders@intracare.nl Website: http://www.intracare.nl	

IDENTIFICATION	NAME AND ADDRESS OF SENDER	NAME & ADDRESS/ REF. OF PATIENT
Safety issue in animals <input type="checkbox"/> in humans <input type="checkbox"/> Lack of expected efficacy <input type="checkbox"/> Withdrawal period issues <input type="checkbox"/> Environmental problems <input type="checkbox"/>	Veterinarian <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other <input type="checkbox"/> Phone: _____ Fax: _____	(according to national law)

PATIENT(S) <i>Animal(s)</i> <input type="checkbox"/> <i>Human(s)</i> <input type="checkbox"/> (for humans fill only age and sex below)						
Species	Breed	Sex	Status	Age	Weight	Reason for treatment
		Female <input type="checkbox"/> Male <input type="checkbox"/>	Neutered <input type="checkbox"/> Pregnant <input type="checkbox"/>			

VETERINARY MEDICINAL PRODUCTS ADMINISTERED BEFORE THE SUSPECTED ADVERSE REACTION <i>(if more products are administered concurrently than the number of boxes available, please duplicate this form)</i>			
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	1	2	3
Name of the veterinary medicinal product (VMP) administered			
Pharmaceutical form & strength (ex: 100 mg tablets)			
Marketing Authorisation number			
Batch number			
Route/site of administration			
Dose / Frequency			
Duration of treatment /Exposure Start Date End Date			
Who administered the VMP? (veterinarian, owner, other)			
Do you think that the reaction is due to this product?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has the Marketing Authorisation Holder (MAH) been informed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

SUSPECTED ADVERSE REACTION DATE _____ / _____ / _____	Time between administration and event in <u>minutes</u> , <u>hours</u> or <u>days</u> _____	Number treated _____ Number reacted _____ Number dead _____	Duration of the adverse reaction in <u>minutes</u> , <u>hours</u> or <u>days</u> _____
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DESCRIPTION OF THE EVENT (*Safety issues in animals or Safety issues in humans/Lack of expected efficacy/Withdrawal period issues/Environmental problems*) – *Please describe:*
 Indicate also if the reaction has been treated, how and with what and what was the result?

OTHER RELEVANT DATA (ATTACH FURTHER PAPERS IF NECESSARY e.g. 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 finger hand joint other
- Other (deliberate....)

Exposure dose:

If you do not agree that your complete name and address are send to the MAH if further information requested, please tick the box.

Date: _____ **Place:** _____ **Name and signature of sender:** _____

Contact point (phone) (if different from the number on page 1)