

## Adverse Event Reporting Form- Avimedical BV 2019

<b>GENERAL</b>			
<b>Topic</b>			
Adverse event in target animal			<input type="checkbox"/>
Adverse event in human			<input type="checkbox"/>
Lack of expected efficacy			<input type="checkbox"/>
Off label use <i>(adverse observation linked to any use not according to SPC (Summary of Product Characteristics) including misuse and abuse of the product)</i>			<input type="checkbox"/>
Withdrawal period issues			<input type="checkbox"/>
Environmental problems			<input type="checkbox"/>
Adverse event in non-target animal			<input type="checkbox"/>
Transmission of infectious agent			<input type="checkbox"/>
<b>Sender</b>	<b>Person who reported the adverse event to the sender</b>		
Animal owner <input type="checkbox"/>	Animal owner		<input type="checkbox"/>
Veterinarian <input type="checkbox"/>	Veterinarian		<input type="checkbox"/>
Distributor <input type="checkbox"/>	Distributor		<input type="checkbox"/>
Other: <input type="checkbox"/> <i>(describe)</i>	Other:		<input type="checkbox"/>
Initial Reporting Date <input type="checkbox"/>	<i>(describe)</i>		
Address Sender			
Country Sender			
(mobile) Phone Sender			
<b>ANIMAL DATA</b>			
no. of animals treated with the VMP:	no. of animals showing signs after treatment with the VMP	no. of animals died after treatment with the VMP	
species	breed/production type		
<u>Physiological status</u>	female <input type="checkbox"/>	male <input type="checkbox"/>	
pregnant <input type="checkbox"/>	neutered <input type="checkbox"/>	lactating <input type="checkbox"/>	
other			
body weight	age		
<u>State of health at time of treatment with VMP</u>			
good <input type="checkbox"/>	fair <input type="checkbox"/>	poor <input type="checkbox"/>	unknown <input type="checkbox"/>
<u>Reason(s) for treatment with VMP (including diagnosis, curative or preventive therapy)</u>			

<b>HUMAN DATA (if applicable)</b>	
<u>Physiological status</u>	
female	<input type="checkbox"/>
male	<input type="checkbox"/>
pregnant	<input type="checkbox"/>
child	<input type="checkbox"/>
adult	<input type="checkbox"/>
lactating	<input type="checkbox"/>
occupation	
name	address
country	mobile phone
contact with treated animal(s)	yes <input type="checkbox"/> no <input type="checkbox"/>
<u>exposure to VMP because of</u>	
treatment animals	<input type="checkbox"/>
exposure through environment	<input type="checkbox"/>
handling VMP	<input type="checkbox"/>
<u>nature of exposure</u>	
inhalation	<input type="checkbox"/>
injection	<input type="checkbox"/>
ingestion	<input type="checkbox"/>
dermal	<input type="checkbox"/>
duration of exposure	
<b>PRODUCT DATA</b>	
trade name	M.A. number
dosage form	batch number
storage details	expiry date
active substance (s)	
<u>treatment details</u>	
route of administration	
dosage	dose frequency
start date treatment	stop date treatment
<u>who administered the VMP</u>	
veterinarian	<input type="checkbox"/>
owner	<input type="checkbox"/>
other	<input type="checkbox"/>
	(describe)
<u>use according to label</u>	
yes	<input type="checkbox"/>
no	<input type="checkbox"/>
unknown	<input type="checkbox"/>
if no, explain	

action taken after reaction

VMP withdrawn       dose VMP reduced       other   
(describe)

did the reaction disappear after stop treatment with VMP

yes       no       not applicable

did the reaction re-appear after re-introduction of VMP

yes       no       not applicable

list other medications given to the animal(s), if applicable  
(name product(s), dosage, length treatment, reason treatment etc)

**DATA ADVERSE EVENT**

Description of the reaction (animal or human)  
(describe all clinical signs, severity, diagnostic tests, necropsy reports, treatment details, recovery details etc)

Were the signs which appeared after treatment with VMP, treated      yes       no

Do you think the reaction was due to VMP      yes       no

Other remarks/notes

**REPORTING**

Does it concern a Serious Adverse Event?      yes       no

**please send this form to Avimedical BV, within 3 business days!**

Attach all source data concerning this event, to this form.

Source data attached?      yes       no

Number of pages

Please send or email this form to:

**Drs. A.A. Oranje, QPPV**  
**Pharmacovigilance@avimed.nl**