Health Canada Santé Canada

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Adverse Event Reporting Form
Veterinary Drugs Directorate (VDD)

This form is for animal owners, veterinary health professionals and drug manufacturers to report suspected adverse events (also known as adverse reactions) in animals, and/or humans exposed to **veterinary drugs**.

This form is **NOT** for veterinary pesticides (e.g. spot-on flea treatments), veterinary biologics (e.g. vaccines) or Veterinary Health Products (e.g. vitamins) – refer below for the correct reporting form:

- **Report a pesticide incident**
- **Notification of Suspected Adverse Events to Veterinary Biologics**
- **Report a side effect to a Veterinary Health Product**

Reporting is important and may help identify previously unrecognized rare or serious adverse events, which may lead to changes to the product's label. Suspected adverse events related to lack of efficacy (i.e. does not work as indicated on the label) and human side effects after exposure to veterinary drugs should also be reported.

Complete this form and submit either by: email: pv-vet@hc-sc.gc.ca **or** fax: (613) 946-1125

If more space is required, or additional information needs to be submitted (e.g. related hospital records or laboratory results), include it in your email or fax. For more information, call: 1 (877) 838-7322

Submission Type: ◯ Initial ◯ Follow-Up	**Report Type:** ◯ Animal adverse event ◯ Human exposure
Section A: Reporter Information	
Name and address:	
Telephone #:	Email:
Preferred method of contact: ◯ Telephone ◯ E-mail	Preferred language: ◯ English ◯ French
Select the one that best describes you: ◯ Veterinarian ◯ Animal Health Technician ◯ Animal Owner ◯ Manufacturer or other (specify):	
Have you reported the adverse event to the drug manufacturer: ◯ Yes ◯ No	
Section B: Animal/Patient Information	
Animal species:	
Animal breed:	
Adverse event relates to: ◯ Single ◯ Group	
Animal age or range for group (specify days, months or years): Age is approximate: ☐	Animal weight or range for group (specify lb, kg): Weight is approximate: ☐

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Animal gender: Select:	Reproductive status: Select:
Overall health status prior to drug administration: ◯ Excellent ◯ Good ◯ Fair ◯ Poor ◯ Critical ◯ Unknown	
Number of animals treated with product:	
Number of animals that reacted:	
Number of animals that died:	
Medical history (pre-existing conditions, medications, reactions to other medications):	

Section C: Adverse Event Information

Description of adverse event (clinical signs, severity, possible contributing factors, treatment):

Adverse event start date (yyyy-mm-dd):	Adverse event end date (yyyy-mm-dd):

Severity of adverse event diminished after stopping using the product?

◯ Yes ◯ No ◯ Not applicable

Adverse event reappeared after re-introducing the product?

◯ Yes ◯ No ◯ Not applicable

Outcome of the adverse event:

◯ Recovered ◯ Under treatment ◯ Alive with permanent health issues ◯ Euthanized ◯ Died ◯ Unknown

Section D: Suspected Product Information

Brand name and/or active ingredient:	Name of drug manufacturer:	
Drug identification number (DIN) on the label:	Expiry date (yyyy-mm):	Lot number:

If there appeared to be a problem with the product (e.g. security seal broken, odd colour/odour, etc.), describe:

Diagnosis and/or reason for using the product:

Dosage form (e.g. tablet, cream, solution):

Treatment start date: (yyyy-mm-dd)	Treatment end date (i.e. when last treatment given): (yyyy-mm-dd)

Duration of product use (specify days, months, years):

Dose administered (strength and quantity):	Frequency (e.g. twice daily):
Route of administration (e.g. oral, topical, injection):	

Was the product used according to the label?

○ Yes ○ Maybe ○ No ○ Do not know

If maybe or no, explain further:

Administered by:

○ Veterinarian/Technician ○ Animal Owner ○ Other (specify):

Were other medications given to the animal(s) at the time of the adverse event (excluding treatment for the adverse event)?

○ Yes ○ No ○ Do not know

If yes:

List the other medications:

Note any related test/laboratory results:

Veterinarian's level of suspicion that the product caused the adverse event, if applicable:

○ High ○ Medium ○ Low ○ Do not know

Animal(s) have been treated with this product or similar in the past?

○ Yes ○ No ○ Do not know

Veterinary Drugs Directorate (VDD)

Tel.: 1-877-838-7322 Fax: 613-946-1125

Email: pv-vet@hc-sc.gc.ca

Website: Adverse veterinary drug reactions

Confidentiality

Information related to the identity of the reporter of the adverse event will be protected under the Privacy Act, and under the Access to Information Act in the case of an access to information request.