Health Canada Santé Canada

Protected B When Completed

Emergency drug release (EDR) follow-up form
Veterinary drugs directorate (VDD)

Complete this form (mandatory) after the drug has been administered and submit by either:
Email: hc.edr-dmu.sc@canada.ca or Fax: 613-946-1125

We will contact you if we require any additional information or clarity regarding your form.

Section A: Veterinary practitioner information		
Veterinary practitioner's name (First Last):		
Hospital/clinic name:		
EDR #:	Telephone #:	Fax #:
Email:		

Section B: Patient Information
Animal patient name/owner's name **or** Production site and producer's name:
Species:
Indication for use of drug:

Section C: Drug information
Drug brand name:
Dosage administered:
Is treatment ongoing? ○ Yes ○ No
Reason for discontinuation (if applicable):
Account for all quantities of drug received
Quantity authorized/received:
Quantity used:
Quantity disposed:
Quantity and Lot # / Expiry of drug retained for future use (needs to be authorized):

Canada

Section D: Treatment response

What was the goal of treatment?

Describe response:

Section E: Safety - Adverse events

Did the patient experience any adverse event[1]? ○ Yes ○ No

If you answered **yes** to the above question, describe the clinical signs observed (including lack of product efficacy):

It is recommended that adverse events be reported by filling out an Adverse Event Reporting Form for Animal Owners and Veterinary Health Professionals. The form can be accessed at:

https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/vet/dar-rim_form-eng_2018-08-03.pdf

[1] An adverse event is any observation in animals, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of a drug for veterinary use.

Section F: Attestation and signature

By signing and checking the boxes below, I attest that:

- ☐ All information above is true and correct to the best of my knowledge
- ☐ I have read and understood my roles and responsibilities outlined in the Food and Drug Regulations
- ☐ I understand that for EDR drugs that are medically important antimicrobials for veterinary use on List A **and** that were not present in Canada at the time of sale (this means I am the person importing the drug), I must report annually to the Veterinary Antimicrobial Sales Reporting (VASR) system of Health Canada on:
  - the total quantity sold or distributed
  - the approximate quantity sold or distributed for each intended animal species

  Email hc.vasr-vavr.sc@canada.ca to be added to the VASR system.

Note that if the EDR drug that is on List A was present in Canada at the time of its sale, the manufacturer will undertake the sales reporting (not the veterinary practitioner).

Veterinary Practitioner's Signature:	Date:

Veterinary Drugs Directorate (VDD)
Holland Cross Complex, Ground Floor,
14-11 Holland Avenue, Postal Locator 3000A, Ottawa, ON, K1A 0K9

Tel.: 613-240-3916 Fax: 613-946-1125

Email: hc.edr-dmu.sc@canada.ca **Website:** Emergency Drug Release

Note: All drugs made available through the EDR program have not been comprehensively reviewed by the Veterinary Drugs Directorate (VDD), Health Canada. Therefore, veterinary practitioners should be vigilant in following the patient's response to treatment, including monitoring for potential adverse events or lack of product efficacy.