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

| Form to be sen | t to: | | | | | | Ref. N | umber | : |
|--|--------|--------------|---------|--------------------|----------|-----------------------------|--------|------------------------------------|---------------------------|
| CID LINES N.V. Waterpoortstraat 2 8900 leper - BE | | | | | | | | | |
| Fax: 003257217879 Phone: 0032475988363 E-mail: pharmacovigilance@cidlines.com Website: www.cidlines.com | | | | | | | | | |
| IDENTIFICATION | | | | NAME AND A | SS OF | SENDER | | NAME & ADDRESS/ REF. OF PATIENT | |
| in animals in humans Lack of expected efficacy Withdrawal period issues Environmental problems | | | Veterir | | :: :: | Other ☐ | | (according to national law) | |
| PATIENT(S) | Animal | (s) 🗌 | | | Hum | man(s) [(for humans fill o | | | l only age and sex below) |
| Species | Breed | Se | х | Status | A | ge | We | ight | Reason for treatment |
| | | Femal Mal | _ | Neutered Pregnant | | | | | |
| VETERINARY MEDICINAL PRODUCTS ADMINISTERED BEFORE THE SUSPECTED ADVERSE REACTION (if more products are administered concurrently than the number of boxes available, please duplicate this form) | | | | | | | | | |
| Name of the veterinary medicinal product (VMP) administered | | | | 1 | | | 2 | | 3 |
| 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 🗌 N | 0 🗌 | Yes | □ No | 0 🗌 | Yes No No |
| Has the Marketing Authorisation Holder (MAH) been informed? | | | | Yes □ N | o 🗌 | Yes | □ No | 0 🗌 | Yes No No |



| SUSPECTED ADVERSE RE- ACTION DATE | Time between admi- nistration and event | Number treated | Duration of the adverse reaction in minutes, hours | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|
| <u> </u> | in minutes, hours or days | Number reacted | <u>or days</u> | | | | | | | |
| / / | <u>uuys</u> | Number dead | | | | | | | | |
| | | ı or Safety issues in humans / Lack of e. | xpected efficacy / Withdrawal | | | | | | | |
| period issues / Environmental problems) - <u>Please describe</u> : | | | | | | | | | | |
| Indicate also if the reaction has been treated, how and with what and what was the result? | | | | | | | | | | |
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| OTHER RELEVANT DATA (ATTACH FURTHER PAPERS IF NECESSARY e.g. investigations carried out or ongoing, a | | | | | | | | | | |
| copy of medical report for human cases) | | | | | | | | | | |
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| | | | | | | | | | | |
| | | | | | | | | | | |
| HUMAN CASE | | | | | | | | | | |
| If the reported case refers t | o a human being, pleas | se also complete the details of exp | osure below | | | | | | | |
| Contact with treated animal | | | | | | | | | | |
| Oral ingestion | | | | | | | | | | |
| Topical exposure | | | | | | | | | | |
| Ocular exposure | | | | | | | | | | |
| Injection exposure | finger | hand joint | other 🗌 | | | | | | | |
| Other (deliberate) | | | | | | | | | | |
| If you do not agree that your complete name and address are sent to the MAH if further information requested, please tick the box: | | | | | | | | | | |
| Date: Place | Date: Place: Name and signature of sender: | | | | | | | | | |
| | | | | | | | | | | |
| Contact point (phone) (if different from the number on page 1) | | | | | | | | | | |