Adverse Events

NUMELVI is a registered veterinary medicinal product for use in dogs. It is therefore subject to pharmacovigilance with all the legal requirements for pharmacovigilance. All observed and suspected adverse events after administration of NUMELVI and any concomitant treatment must be documented on the adverse event reporting forms and reported to the Sponsor's Representative immediately, but not later than three (3) calendar days. The veterinarian may notify the Sponsor's Representative by fax, email, phone, in person or other means of communication. An overview of all adverse events will be prepared after completion of the clinical impression program.

An adverse event is any observation in animals, whether considered to be product related or not , that is unfavourable and unintended and occurs after the use of the veterinary medicinal product (on-label and off-label). In addition to suspected adverse reactions, an adverse event following the use of a veterinary medicinal product also includes events related to suspected lack of expected efficacy, potential environmental problems, residue violation and suspected transmission of an infectious agent. It also includes any adverse reactions in humans after exposure to a veterinary medicinal product (serious and non-serious).

The period of observation for adverse events ends at least one day after the last dose of NUMELVI for each dog.

Adverse events suspected to result from concurrent illnesses and worsening of disease should also be included. Adverse events should be described as clinical signs using standard veterinary medical terminology to avoid the use of vague, ambiguous or colloquial language. All examinations and treatments related to the adverse event must be documented.

Product Quality Complaints

A product quality complaint is any complaint or information relating to the quality or technical nature of any veterinary medicinal product including, without limitation, the identity, strength, quality, purity, defect, ingredients, or components of a veterinary product or its labelling, or contamination of, or other change or deterioration in, a veterinary medicinal product. Any product quality complaints including, but not limited to, deterioration or contamination of any product, or any mistake in the labelling of any product, will be documented and reported to the Sponsor's Representative immediately, but not later than three (3) business days. The Veterinarian may notify the Sponsor's Representative by fax, email, phone, in person or other means of communication.

When you login to the site for the first time, before entering cases, you will be asked to read the text below and check a box to confirm you understood what is an adverse event and how to report it: ☐ *I certify that I have read and understood the requirements and responsibilities for Adverse Event reporting in the Clinical Impression Program*. If you do not confirm, you won't be able to proceed or participate.