

Application Summary

Application number:	ERMA200125, NOR002
Application type:	Notified, Importation or manufacture for release, Category A
Applicant contact:	Ansam Ganim
Applicant:	Norbrook NZ Ltd c/- PharmVet Solutions PO Box 78037 Grey Lynn Auckland 1245 New Zealand
Purpose:	To import NOR002 as a non-steroidal anti-inflammatory injection for use in dogs, cats and horses.
Date formally received:	5 October 2009

Application Summary prepared by Norbrook NZ Ltd

NOR002 is a non-steroidal anti-inflammatory formulation with analgesic action. They are indicated for analgesia and reduction of inflammation, for example in degenerative joint disease of the dog, cat and horses.

This application is being made to gain approval for NOR002 to be imported and released in New Zealand. Products containing the same active ingredient are already on the market; however this formulation requires assessment according to the HSNO Act due to the higher strength of the active ingredient.

NOR002 is expected to trigger thresholds for acute oral toxicity, sensitization, target organ effects; and ecotoxic effects (terrestrial vertebrate).

The main risks associated with this product are those to the user if not handled appropriately, or to Terrestrial vertebrate in the case of accidental release to the environment or inappropriate disposal. The likelihood of these risks are judged to be minimal as these events are unlikely; and in the event that they did occur would be of localized and of short duration. The product labeling and the defined method of administration will further control these risks. The toxicological and eco-toxicological properties of the product will be managed by observing appropriate handling procedures, which will be provided in a Safety Data Sheet and through labelling. Therefore residual risks to persons or the environment resulting from release of this product will be insignificant.

Potential Benefits – Financial & social

- The product is registered by the ACVM, NOR002 is one of the few non-steroidal anti-inflammatory ingredient analgesic injections for cattle and horses in NZ. NOR002 is intended to be administered to food producing animals (horses) and companion animals (dogs & cats).
- The substance also has a combination of certain toxic and ecotoxic properties.
- Non-steroidal anti-inflammatory are rapidly and well absorbed after administration.

- Indicated for anti-inflammatory, analgesic, antipyretic for dogs, cats & horses. Indicated in cattle for the treatment inflammatory conditions such as acute mastitis and pneumonia. and in horses for the control of post-operative inflammation, and musculoskeletal problems.
- Administration directly into the animal system minimises the chance of spillage.