



22 June 2018  
EMA/CVMP/381884/2018  
Committee for Medicinal Products for Veterinary Use

## Summary of opinion<sup>1</sup> (initial authorisation)

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### LONGRANGE

International non-proprietary name (INN): eprinomectin

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a negative opinion<sup>2</sup>, recommending the refusal of the granting of a marketing authorisation for the veterinary medicinal product LONGRANGE, 50 mg/ml, prolonged-release solution for injection.

The applicant Merial applied for the following indication(s):

Treatment of the following parasites:

- Gastrointestinal roundworms (Adult and L4): *Ostertagia ostertagi/lyrata*, *Cooperia oncophora/surnabada*, *C. punctata*, *Haemonchus contortus*, *Trichostrongylus axei*, *T. colubriformis*, *Bunostomum phlebotomum*, *Nematodirus helvetianus*, *Oesophagostomum radiatum*.
- Lungworm (Adults and L4): *Dictyocaulus viviparus*;

Prevention of reinfections with the following parasites:

- Gastrointestinal roundworms: *Ostertagia ostertagi/lyrata*, *Trichostrongylus colubriformis*, *Haemonchus contortus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, *Cooperia oncophora/surnabada*, *C. punctata*, *Trichostrongylus axei*.
- Lungworms: *Dictyocaulus viviparus*

Administration at the time of turnout will also treat concomitant infestations with the following ectoparasites:

- Warbles (parasitic stages): *Hypoderma bovis*, *Hypoderma lineatum* Mange mites: *Sarcoptes scabiei* var. *bovis*
- Sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenoptes capillatus*  
Horn flies: *Haematobia irritans*.

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<sup>1</sup> Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the opinion.

<sup>2</sup> Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.



The active substance of LONGRANGE is eprinomectin.

The grounds for the negative opinion relate to environmental issues.

The CVMP, on the basis of the data submitted, considers that the benefit to risk balance for LONGRANGE was not demonstrated to be favourable and therefore cannot recommend the granting of a marketing authorisation.