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HYOGEN EMULSION FOR INJECTION

Authorised

- Mycoplasma hyopneumoniae, strain 2940, Inactivated

Product identification

Medicine name:
HYOGEN EMULSION FOR INJECTION

Active substance:
Mycoplasma hyopneumoniae, strain 2940, Inactivated

Target species:
Pig (for fattening)

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Mycoplasma hyopneumoniae, strain 2940, Inactivated
328.00 enzyme-linked immunosorbent assay unit / 2.00 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Pig (for fattening)**
  - All relevant tissues. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI09AB13

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Denmark

Available in:
Denmark

Package description:
Cardboard box of 1 bottle of 50 ml (1x25 doses)
Cardboard box of 5 bottles of 250 ml (5x125 doses)
Cardboard box of 1 bottle of 250 ml (1x125 doses)
Cardboard box of 5x200 ml in 5 bottles of 250 ml (5x100 doses)
Cardboard box of 200 ml in 1 bottle of 250 ml (1x100 doses)
Cardboard box of 5 bottles of 200 ml (5x100 doses)
Cardboard box of 1 bottle of 200 ml (1x100 doses)
Cardboard box of 5 bottles of 100 ml (5x50 doses)
Cardboard box of 1 bottle of 100 ml (1x50 doses)
Cardboard box of 5 bottles of 50 ml (5x25 doses)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - New active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Ceva-Phylaxia Zrt.

Marketing authorisation date:
17/06/2015

Manufacturing sites for batch release:
Ceva-Phylaxia Zrt.

Responsible authority:
Danish Medicines Agency

Authorisation number:
53768

Date of authorisation status change:
17/06/2015

Reference member state:
France

Procedure number:
FR/V/0278/001

Concerned member states:
Austria Belgium Bulgaria Croatia Cyprus Czechia Denmark Estonia Germany Greece Hungary Ireland Italy Latvia Lithuania Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden

United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

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