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BioEquin FH, Emulsion for injection

Authorised

- Influenza A virus, subtype H3N8, strain A/equine/Brno/08, Inactivated
- Equine herpesvirus 1, Inactivated
- Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, Inactivated

Product identification

Medicine name:
BioEquin FH, Emulsion for injection

Active substance:
Influenza A virus, subtype H3N8, strain A/equine/Brno/08, Inactivated

Equine herpesvirus 1, Inactivated

Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, Inactivated

Target species:
Horse

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Influenza A virus, subtype H3N8, strain A/equine/Brno/08, Inactivated
6.00 log2 haemagglutination inhibiting unit(s) / 1.00 Dose

Equine herpesvirus 1, Inactivated
2.10 log10 virus neutralising unit(s) / 1.00 Dose

Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, Inactivated
6.00 log2 haemagglutination inhibiting unit(s) / 1.00 Dose

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Horse**
  - Meat. 0 day
  - Milk. 0 hour

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI05AA04

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

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Authorisation status:
Valid

Authorised in:
Hungary

Package description:
Glass Vial
Glass Vial
Glass Vial
Glass Vial
Glass Vial

Additional information

Entitlement type:
Marketing Authorisation

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

Marketing authorisation holder:
Bioveta a.s.

Marketing authorisation date:
24/11/2014

Manufacturing sites for batch release:
Bioveta a.s.

Responsible authority:
Directorate Of Veterinary Medicinal Products

Authorisation number:
3606/X/14 NÉBIH ÁTI

Date of authorisation status change:
24/11/2014

Reference member state:
Czechia

Procedure number:
CZ/V/0127/001

Concerned member states:
Austria Belgium Denmark Estonia Finland France Germany Hungary Ireland Italy Latvia Lithuania Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden

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

Documents

Combined File of all Documents