

BioEquin FH, Emulsion for injection

Authorised

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

Product identification

Medicine name:

BioEquin FH, Emulsion for injection

Active substance:

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

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

Equine herpesvirus 1, 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

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

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

Authorisation status:

Valid

Authorised in:

Estonia

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:

21/12/2014

Manufacturing sites for batch release:

Bioveta, a.s.

Responsible authority:

State Agency Of Medicines

Authorisation number:

1886

Date of authorisation status change:

21/12/2014

Reference member state:

Czechia

Procedure number:

CZ/V/0127/001

Concerned member states:

Estonia Hungary Latvia Lithuania Poland Romania Slovakia Slovenia

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

Documents

Summary of Product Characteristics

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Combined File of all Documents