DIVENCE Tetra (--) Lyophilisate and solvent for emulsion for injection

Authorised

- Bovine respiratory syncytial virus, strain Lym-56, Live
- Bovine parainfluenza virus 3, strain SF-4, Inactivated
- Bovine viral diarrhoea virus 1, protein E2 (recombinant)
- Bovine viral diarrhoea virus 2, protein E2 (recombinant)

Product identification

Medicine name:
DIVENCE Tetra (--) Lyophilisate and solvent for emulsion for injection

Active substance:
Bovine respiratory syncytial virus, strain Lym-56, Live

Bovine parainfluenza virus 3, strain SF-4, Inactivated

Bovine viral diarrhoea virus 1, protein E2 (recombinant)

Bovine viral diarrhoea virus 2, protein E2 (recombinant)

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Bovine respiratory syncytial virus, strain Lym-56, Live

Presentation_strength:$10^{5,2}$ - $10^{6,5}$ CCID50 Comments:lyophilisate Index:0

Bovine parainfluenza virus 3, strain SF-4, Inactivated

Presentation_strength:≥ 206.2 EU Comments:lyophilisate Index:1

Bovine viral diarrhoea virus 1, protein E2 (recombinant)

Presentation_strength:≥ 31.6 EU Comments:lyophilisate Index:2

Bovine viral diarrhoea virus 2, protein E2 (recombinant)

Presentation_strength:≥ 21.0 EU Comments:lyophilisate Index:3

Pharmaceutical form:

Lyophilisate and solvent for emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - All relevant tissues. 0 day 0 Days

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AH

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Austria , Belgium , Bulgaria , Croatia , Cyprus , Czechia , Denmark , Estonia , Finland , France , Germany , Greece , Hungary , Iceland , Ireland , Italy , Latvia , Liechtenstein , Lithuania , Luxembourg , Malta , Netherlands , Norway , Poland , Portugal , Romania , Slovakia , Slovenia , Spain , Sweden , United Kingdom (Northern Ireland)

Package description:
Packaging:Lyophilisate: vial (glass); Solvent: vial (PET), Package_size:1 vial Lyophilisate, 1 vial solvent, Content:Lyophilisate: 20 doses; Solvent: 40 ml
Packaging:Lyophilisate: vial (glass); Solvent: vial (PET), Package_size:1 vial Lyophilisate, 1 vial solvent, Content:Lyophilisate: 10 doses; Solvent: 20 ml
Packaging:Lyophilisate: vial (glass); Solvent: vial (PET), Package_size:1 vial Lyophilisate, 1 vial solvent, Content:Lyophilisate: 5 doses; Solvent: 10 ml

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application - new active substance (Article 8 of Regulation (EU) 2019/6)

Marketing authorisation holder:
LABORATORIOS HIPRA,S.A.

Marketing authorisation date:
10/05/2024

Manufacturing sites for batch release:
Laboratorios Hipra S.A.

Responsible authority:
European Commission

Authorisation number:
This information is not available for this product.

Date of authorisation status change:
10/05/2024

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

Documents

Combined File of all Documents

English (PDF)
Published on: 8/12/2025
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