DIVENCE IBR Marker Live Lyophilisate and solvent for emulsion for injection

Authorised

- Bovine herpesvirus 1, strain CEDDEL, gE- tk- double-gene deleted, Live

Product identification

Medicine name:
DIVENCE IBR Marker Live Lyophilisate and solvent for emulsion for injection

Active substance:
Bovine herpesvirus 1, strain CEDDEL, gE- tk- double-gene deleted, Live

Target species:
Cattle

Route of administration:
Intramuscular use

Product details

Active substance and strength:
Bovine herpesvirus 1, strain CEDDEL, gE- tk- double-gene deleted, Live

Presentation_strength:$10^{6,3}$ - $10^{7,6}$ CCID50 Comments:lyophilisate Index:0

Pharmaceutical form:

Lyophilisate and solvent for emulsion for injection

Withdrawal period by route of administration:

Intramuscular use:

- **Cattle**
  - All relevant tissues. 0 day Zero days

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI02AD01

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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 Lyophlisate, 1 vial solvent, Content:Lyophilisate: 5 doses; solvent: 10 ml
Packaging:Lyophilisate: vial (glass); Solvent; vial (PET), Package_size:1 vial Lyophlisate, 1 vial solvent, Content:Lyophilisate: 20 doses; solvent: 40 ml
Packaging:Lyophilisate: vial (glass); Solvent; vial (PET), Package_size:1 vial Lyophlisate, 1 vial solvent, Content:Lyophilisate: 50 doses; solvent: 100 ml
Packaging:Lyophilisate: vial (glass); Solvent; vial (PET), Package_size:1 vial Lyophlisate, 1 vial solvent, Content:Lyophilisate: 40 doses; solvent: 80 ml

Additional information

Entitlement type:

Marketing Authorisation

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

Marketing authorisation holder:
LABORATORIOS HIPRA, S.A.

Marketing authorisation date:
9/08/2024

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:
9/08/2024

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

Documents

Combined File of all Documents

English (PDF)
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