ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPIZOVAC suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of vaccine contains:

Active substances:

Epizootic haemorrhagic disease virus (EHDV), serotype 8, strain EHDV8 SPA 2022/LCV_03 LCV Cod.:O78, inactivated $10^{5.5}CCID_{50}$*

*$CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation.

Adjuvants:

Aluminium hydroxide ..... 6 mg
Purified saponin (Quil A) .....0.05 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Sodium chloride	
Disodium phosphate	
Potassium phosphate	
Water for injections	

White or pinkish-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

For the active immunisation of cattle to prevent viraemia caused by serotype 8 of the epizootic haemorrhagic disease virus.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.

Duration of immunity: not established

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive cattle, including those with maternal antibodies.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site inflammation* Injection site nodule** Injection site pain*** Elevated temperature****

* Diameter up to 8 cm.
** Diameter of less than 6 cm, persisting for up to 3 weeks.
*** Upon palpation, at days 2 - 3 post vaccination.
**** Not exceeding 1.5 ˚C, during the 48 hours following vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
No negative impact is expected in pregnant cows. No negative impact on the milk-yield using the vaccine in lactating cows is expected.

Fertility:
The safety of the vaccines has not been established in breeding males. In this category of animals, the vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian and/or National Competent Authorities on the current vaccination policies.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.
Subcutaneous use.

Primary vaccination
From 2 months of age.
Administer two doses of 4 mL subcutaneously 3 weeks apart.

Revaccination
Not established.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI02AA

To stimulate active immunity of cattle against epizootic haemorrhagic disease virus, serotype 8.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 52 mL, 100 mL or 252 mL with bromobutyl stoppers and aluminium seals.

Pack sizes:
Cardboard box with 1 bottle containing 52 mL
Cardboard box with 1 bottle containing 100 mL
Cardboard box with 1 bottle containing 252 mL

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/341/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

EXCEPTIONAL CIRCUMSTANCES:
Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES

This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

Description	Due date
Completion of the development of a potency test on the finished product. Data should be provided as soon as available.	March 2027
Data from the stability studies (up to 18 months) should be provided upon completion, to confirm the shelf life under the recommended storage conditions for the inactivated EHDV antigen. Any out of specification result should be communicated immediately to the European Medicines Agency.	February 2026
Data from the stability studies (up to 21 months) should be provided upon completion, to confirm the accepted shelf life of 18 months under the recommended storage conditions for the finished product. Any out of specification result should be communicated immediately to the European Medicines Agency. As soon as a potency test is available, this is expected to be included in the stability program. Stability data on the 52 mL presentation are expected.	June 2026
A study on the duration of immunity should be conducted and data should be provided as soon as they become available.	February 2027

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (52 mL, 100 mL and 252 mL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPIZOVAC suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL of vaccine contains:

Epizootic haemorrhagic disease virus (EHDV), serotype 8, strain EHDV8 SPA 2022/LCV_03 LCV Cod.:O78, inactivated $10^{5.5}CCID_{50}$*

*$CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation.

3. PACKAGE SIZE

52 mL
100 mL
252 mL

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

14. MARKETING AUTHORISATION NUMBERS

EU/2/25/341/001-003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 52 mL, 100 mL and 252 mL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPIZOVAC suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL of vaccine contains:

Epizootic haemorrhagic disease virus (EHDV), serotype 8, strain EHDV8 SPA 2022/LCV_03 LCV Cod.:O78, inactivated $10^{5.5}CCID_{50}$*

*$CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation.

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CZ Vaccines S.A.U.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

HEPIZOVAC suspension for injection for cattle

2. Composition

Each mL of vaccine contains:

Active substances:

Epizootic haemorrhagic disease virus (EHDV), serotype 8, strain EHDV8 SPA 2022/LCV_03 LCV Cod.:O78, inactivated $10^{5.5}CCID_{50}$*

*$CCID_{50}$: 50% cell culture infective dose equivalent to titre prior inactivation.

Adjuvants:
Aluminium hydroxide ..... 6 mg
Purified saponin (Quil A) .....0.05 mg

Excipients:
Thiomersal ..... 0.1 mg

White or pinkish-white suspension.

3. Target species

Cattle

4. Indications for use

For the active immunisation of cattle to prevent viraemia caused by serotype 8 of the epizootic haemorrhagic disease virus.

Onset of immunity: 3 weeks after completion of the primary vaccination scheme.

Duration of immunity: not established

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

No information is available on the use of the vaccine in seropositive cattle, including those with maternal antibodies.

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
No negative impact is expected in pregnant cows. No negative impact on the milk-yield using the vaccine in lactating cows is expected.

Fertility:
The safety of the vaccine has not been established in breeding males. In this category of animals, the vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian and/or National Competent Authorities on the current vaccination policies.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:
Not applicable

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):
Injection site inflammation*
Injection site nodule**
Injection site pain***
Elevated temperature****

* Diameter up to 8 cm.
** Diameter of less than 6 cm, persisting for up to 3 weeks.
*** Upon palpation, at days 2 - 3 post vaccination.
****Not exceeding 1.5 ˚C, during the 48 hours following vaccination.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Primary vaccination
From 2 months of age.
Administer two doses of 4 mL subcutaneously 3 weeks apart.

Revaccination
Not established.

9. Advice on correct administration

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/341/001-003

Pack sizes:

Cardboard box with 1 bottle containing 52 mL
Cardboard box with 1 bottle containing 100 mL
Cardboard box with 1 bottle containing 252 mL

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
CZ Vaccines S.A.U.
A Relva s/n – Torneiros
36410 O Porriño
Pontevedra
Spain
Tel: +34 986 330 400

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien
Ceva Santé Animale N.V.
Avenue de la Métrologie 6
1130 Bruxelles
België/Belgique/Belgien
Tél/Tel: +800 35 22 11 51

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