HEPIZOVAC®

Product information

CONTENTS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPIZOVAC suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

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)

Sodium chloride

Disodium phosphate

Potassium phosphate

Water for injections

3. PHARMACEUTICAL FORM

Suspension for injection.

White or pinkish-white suspension.

4. CLINICAL INFORMATION

4.1 | Target species

Cattle

4.2 | Indications for use for each target species

Cattle:

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.

4.3 | Contraindications

None.

4.4 | Special warnings

Vaccinate healthy animals only.

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

4.5 | Special precautions for use

Special precautions for 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.

4.6 | Adverse events

Cattle:
Very common (>1 animal / 10 animals treated): injection site inflammation (diameter up to 8 cm); injection site nodule (diameter of less than 6 cm, persisting for up to 3 weeks); injection site pain (upon palpation, at days 2 - 3 post vaccination); elevated temperature (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.

4.7 | 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.

4.8 | 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.

4.9 | Amounts to be administered and administration route

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.

Re-vaccination:
Not established.

4.10 | Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 | Withdrawal period(s)

Meat, milk and offal: Zero days.

5. IMMUNOLOGICAL INFORMATION

ATCvet code: QI02AA.

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

6. PHARMACEUTICAL PARTICULARS

6.1 | Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.2 | 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.

6.3 | Special precautions for storage

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

6.4 | 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.

Package 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.

6.5 | Special precautions for the disposal of unused veterinary medicinal product 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.