SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VEPURED suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Recombinant verotoxin 2e of *E. coli* ..... RP* ≥ 1.50
* RP – relative potency (ELISA)

Adjuvants:
Aluminium hydroxide (Al^{3+})..... 2.117 mg
DEAE-dextran .....10 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Whitish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the target species

Active immunisation of piglets from 2 days of age to prevent mortality and reduce clinical signs of oedema disease (caused by verotoxin 2e produced by *E. coli*) and to reduce the loss of daily weight gain during the finishing period in the face of infections with verotoxin 2e producing *E. coli* until slaughter from 164 days of age.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 112 days after vaccination.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvants or to any of the excipients.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Very common adverse reactions:
- Mild inflammation at the injection site (< 5 cm in diameter) that typically resolves within three days post-vaccination without treatment.
- Mild depression during the day of vaccination.
- Temperature rise of maximum 1.1 °C was observed. Temperatures returned to normal within 24 hrs.

Emesis, recumbency, convulsion, lethargy and loss of consciousness occur in very rare cases within a few minutes after vaccination. The animals mostly start to recover within around 15 minutes. In case of severe anaphylactic-type reactions appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

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

Intramuscular use.

Allow the vaccine to reach room temperature (15–25 ºC) before administration.
Shake well before use.

Administer a single intramuscular injection of 1 ml in the neck muscles.

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

No information is available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia).
ATC vet code: QI09AB02.

The vaccine consisting of recombinant verotoxin 2e stimulates an active immunity against VT2e toxin produced by the causative agent of oedema disease in pigs. Vaccinated animals are able to neutralise the VT2e toxin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE-dextran
Simethicone
Sodium hydroxide
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
Shelf life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

Polyethylene (PET) vials of 10, 50, 100 and 250 ml.
The vials are closed with a bromobutyl rubber stopper and aluminium cap.

Cardboard box with 1 vial of 10 doses (10 ml).
Cardboard box with 10 vials of 10 doses (10 ml).
Cardboard box with 1 vial of 50 doses (50 ml).
Cardboard box with 1 vial of 100 doses (100 ml).
Cardboard box with 1 vial of 250 doses (250 ml).

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra S.A.
Avda la Selva 135
17170 Amer (Girona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5012

9. DATE OF FIRST AUTHORISATION

18 July 2017

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 15 March 2022