SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRASUIS-P/E, suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 2 ml contains:

Active substances:

Inactivated Porcine Parvovirus, strain NADL-2: HIA ≥ 1/128 (*).

Inactivated *Erysipelothrix rhusiopathiae*, strain R32E11: IRPC ≥ 49.2 (**).

(*) Enough quantity to induce a serological response in guinea pigs equal to or higher than 1/128 HIA (Haemagglutination inhibition antibody).
(**) Enough quantity to induce a serological response in vaccinated mice equal to or higher than 49.2.

Adjuvant:
Aluminium hydroxide gel (expressed as mg of Aluminium): 0.6 mg.

Excipient(s):
Thiomersal: 0.2 mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Pinkish homogeneous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Swine.

4.2 Indications for use, specifying the target species

Active immunization of gilts, sows and boars from 6 months of age onwards, to reduce reproductive disorders caused by Porcine Parvovirosis (PPV) and to reduce reproductive problems and acute clinical signs from Erysipelas.

Onset of immunity was shown 21 days following the second vaccination by challenge with *Erysipelothrix rhusiopathiae* and 21 days after finished vaccination by serology against PPV. Duration of immunity has been demonstrated for 5 months for *Erysipelithrix rhusiopathiae* and 6 months for PPV, respectively.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate unhealthy animals.

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

In case of accidental self-administration, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Transient temperature increases < 1ºC may occur during the first 24 hours following vaccination.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Vaccination must be carried out no later than two weeks before mating/artificial insemination.

Lactation:
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other has not been demonstrated.

4.9 Amounts to be administered and administration route

2 ml / pig by intramuscular injection in the neck muscles behind the ear.
It s recommended that the vaccine should be allowed to warm to a temperature of between +15 ºC and +25 ºC before administration.
Shake before use.

In absence of maternally derived antibodies (from 6 months of age onwards) administer 2 doses 3 weeks apart. The second dose should be administered at least 2 weeks before mating/artificial insemination.

Usually the vaccination against Porcine Parvovirus is not effective when administered to animals younger than 6 months of age. Monovalent vaccines against Swine Erysipelas shall be administered in these cases.

Revaccination should be done during the lactation period, at least 2 weeks before mating/artificial insemination, or every 6 months.

Boars: basic immunization with 2 doses 3 weeks apart and revaccination every 6 months.

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

No known risks.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Inactivated Porcine Parvovirus vaccine + inactivated Erysipelothrix vaccine.

ATCvet code: QI09AL01.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Thiomersal
Dimeticone
Water for injections

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.
Do not mix with any other medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

The container consists of coloured 20 ml vial of type I glass (10 doses presentation), coloured 50 ml vials of type II glass (25 doses presentation) and coloured 100 ml vials of type II glass (50 doses presentation), all with rubber stoppers and aluminium caps.

Package sizes:
Box of 10 vials of 10 doses (10 x 20 ml).
Box of 10 vials of 25 doses (10 x 50 ml).
Box of 1 vial of 50 doses (1 x 100 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 products 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(S)

17255

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16 April 2004 / 16 April 2009

10 DATE OF REVISION OF THE TEXT

3 April 2009

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.