

PACKAGE LEAFLET

HIPRASUIS-P/E
Suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

LABORATORIOS HIPRA, S.A.
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2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRASUIS-P/E. Suspension for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

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: Thiomersal: 0.2 mg.

Pinkish homogeneous suspension for injection.

4. INDICATIONS

Active immunization of gilts, sows and boars from 6 months of age onwards, to reduce reproductive disorders caused by Porcine Parvovirus (PPV) and to reduce 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.

5. CONTRAINDICATIONS

None known.

6. ADVERSE REACTIONS

Transient temperature increases $< 1^{\circ}\text{C}$ may occur during the first 24 hours following vaccination.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Swine.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

2 ml / pig by intramuscular injection in the neck muscles behind the ear.

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.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended that the vaccine should be allowed to warm to a temperature of between +15 °C and +25 °C before administration. Shake before use.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Keep the container in the outer carton in order to protect from light.

Do not use after the expiry date stated on the label.

Shelf-life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Do not vaccinate unhealthy animals.

Vaccination must be carried out no later than two weeks before mating/artificial insemination. Can be used during lactation.

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.

Do not mix with any other vaccine or immunological product.

Do not mix with any other medicinal product.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

3 April 2009

15. OTHER INFORMATION

Package sizes:

10 vials of 10 doses (10 x 20 ml).

10 vials of 25 doses (10 x 50 ml).

1 vial of 50 doses (1 x 100 ml).

Not all pack sizes may be marketed.