Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRABOVIS-4

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition per dose (3 ml) of vaccine:

Inactivated Infectious Bovine Rhinotracheitis Virus (IBR), strain LA	≥ 10^7 $TCID_{50}$
Inactivated Parainfluenza-3 Virus (PI3), strain SF4	≥ 480 HAU
Inactivated Bovine Diarrhoea Virus (BVD), strain NADL	≥ 10^6 $TCID_{50}$
Live Bovine Respiratory Syncytial Virus, strain Lym-56	≥ 10^5 $TCID_{50}$
Adjuvant	
Aluminium hydroxide gel (as Aluminium per dose)	5.39-6.67 mg
Saponine	0.30 mg
Thiomersal	0.30 mg
Excipient q.s	3.00 ml

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Powder for reconstitution for suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle from 2 months of age.

4.2 Indications for use, specifying the target species

To stimulate active immunity against IBR, PI3, BVD and BRS viruses in cattle.

For active immunisation of cattle to reduce clinical signs of Bovine Respiratory Syndrome associated with Infectious Bovine Rhinotracheitis, Parainfluenza-3 virus and Bovine Viral Diarrhoea virus, as well as to reduce virus shedding and duration of shedding of BRSV.
Onset and duration of immunity: Immunity conferred by HIPRABOVIS-4 appears at 30-50 days after first vaccination and lasts for at least 1 year.

4.3 Contraindications

None.

4.4 Special warnings for each target species

It is advisable to vaccinate all animals in a herd in order to minimise spread of infection.

Maternal antibodies will reduce the efficacy of the vaccine if administered to calves less than 2 months of age.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.

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

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Wash and disinfect hands after use.

4.6 Adverse reactions (frequency and seriousness)

Anaphylactic reactions may develop in sensitised animals. In such a case, administer epinephrine or a similar drug.

4.7 Use during pregnancy, lactation or lay

HIPRABOVIS-4 can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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 (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

Resuspend the freeze-dried fraction with the liquid fraction as follows: withdraw approximately 8 ml of the liquid fraction and use this to reconstitute the freeze-dried fraction. Shake gently until completely dissolved. Withdraw the resulting suspension and mix with the remaining liquid fraction. Shake gently to obtain a homogeneous solution.

1 dose: 3 ml.
Route of administration: intramuscular injection in the neck muscles.

Basic vaccination scheme:
In cattle from 2 months of age onwards, administer one dose followed by a second dose 21-30 days later.

Re-vaccination scheme:
A 3 ml booster dose should be given every 12 months.

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

Small increases in body temperatures and a slight swelling at the injection site were observed in animals receiving a double dose of the vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

HIPRABOVIS-4 is a combined tetravalent vaccine intended to stimulate active immunity against Infectious Bovine Rhinotracheitis virus, Parainfluenza-3 virus, Bovine Viral Diarrhoea virus and Bovine Respiratory Syncytial virus.ATCvet code: QI02AH (Live and inactivated viral vaccines for bovidae).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Gelatin
Povidone 30
Sodium Chloride
Sucrose
Monosodium glutamate
Potassium Chloride

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

24 months.Use immediately following reconstitution

6.4 Special precautions for storage

Store refrigerated 2°C - 8°C.
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Freeze-dried fraction: the container is composed by neutral colourless glass flasks of 10 ml (5 and 30 doses) classified as Type I (Eur. Phar.), grey elastomer Type I closures (Eur. Phar.) and detachable aluminium caps.

Liquid fraction: the container is composed by coloured glass flasks of 20 ml (5 doses) Type I (Eur. Phar.), coloured glass flasks of 100 ml (30 doses) Type II (Eur. Phar.), grey elastomer Type II closures (Eur. Phar.) and capsules made of anodised aluminium.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7 MARKETING AUTHORISATION HOLDER

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Avda. La Selva 135
17170 - Amer (Girona)
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10846/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 June 2003
Date of last renewal: 05 June 2008

10 DATE OF REVISION OF THE TEXT

June 2006

PROHIBITION OF SALE, SUPPLY AND/OR USE

The Diseases of Animals Act, 1966 (Control on Animal and Poultry Vaccines) Order 2002 (S.I. No. 528 of 2002) applies in the case of Infectious Bovine Rhinotracheitis. The Veterinary Product Authorisation is therefore subject to specific licensing requirements under the aforementioned legislation. The Immunological Animal Remedy shall not be imported, sold or administered except in accordance with a licence granted under the Statutory Instrument No 528 of 2002.