LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LAPINJECT® VHD
Inactivated vaccine against rabbit haemorrhagic disease, for rabbits

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

For one dose of vaccine:
Calicivirus of rabbit hemorrhagic disease 1 PD_{100}*
Strain 3116-AP (suspension of inactivated virus)
Mineral oil .....104.125 mg
Thiomersal ..... 0.05 mg
Excipient q.s. 1 dose of 0.5 ml

* Protective Dose 100% tested in rabbits.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

-Box of 1 glass vial (2,5 ml) of 5 doses
-Box of 1 glass vial (5 ml) of 10 doses
-Box of 10 glass vials (5 ml) of 10 doses
-Box of 1 glass vial (10ml) of 20 doses
-Box of 10 glass vials (10 ml) of 20 doses
-Box of 1 glass vial (20 ml) of 40 doses
-Box of 2 glass vials (20 ml) of 40 doses
-Box of 10 glass vials (20 ml) of 40 doses
-Box of 1 glass vial (100 ml) of 200 doses

5. TARGET SPECIES

Rabbit

6. INDICATION(S)

For active immunisation of rabbit to prevent mortality caused by RHD virus
Onset of immunity: 6 days
Duration of immunity: 1 year

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero Days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP:
Shelf-life after reconstitution: 8-10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport between + 2 °C and + 8 °C.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 the local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Limited
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LAPINJECT® VHD
Inactivated vaccine against rabbit haemorrhagic disease, for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

For one dose of vaccine:
Calicivirus of rabbit hemorrhagic disease 1 PD_{100}*
Strain 3116-AP (suspension of inactivated virus)
Mineral oil .....104.125 mg
Thiomersal ..... 0.05 mg
Excipient q.s. 1 dose of 0.5 ml

* Protective Dose 100% tested in rabbits.

4. ROUTE(S) OF ADMINISTRATION

Administered subcutaneously

5. WITHDRAWAL PERIOD

Withdrawal period: Zero Days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Shelf-life after reconstitution: 8-10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

LAPINJECT® VHD

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

Marketing authorisation holder
Ceva Animal Health Limited
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

Manufacturer for the batch release
Laboratories HIPRA SA
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

LAPINJECT® VHD
Inactivated vaccine against rabbit haemorrhagic disease, for rabbits

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

For one dose of vaccine:
Calicivirus of rabbit hemorrhagic disease 1 PD_{100}*
Strain 3116-AP (suspension of inactivated virus)
Mineral oil .....104.125 mg
Thiomersal ..... 0.05 mg
Excipient q.s. 1 dose of 0.5 ml

* Protective Dose 100% tested in rabbits.

4. INDICATION(S)

For active immunisation of rabbit to prevent mortality caused by RHD virus
Onset of immunity: 6 days
Duration of immunity: 1 year

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A local inflammatory reaction at the point of injection may appear, resulting in a sclerous cicatricial granuloma, which may persist for a period of at least 28 days in the fat cells.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Rabbit

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

1 dose of 0.5 ml per rabbit, administered subcutaneously

ADVICE ON CORRECT ADMINISTRATION

PRIMARY VACCINATION: 1 injection in rabbits from the age of 5 weeks.

BOOSTER: 1 injection every 12 months

Where intensive breeding under commercial farming conditions is undertaken it is recommended to vaccinate breeding does every 6 to 12 months, depending of the turnover and the sanitary situation of the farm

MODE OF ADMINISTRATION: Keep the vial at ambient temperature (approximately 25 °C) a few minutes before the administration of the vaccine. Agitate the vial before use, to obtain a homogeneous emulsion. The content of the vial must be used in a working day (8-10 hours).

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport between + 2 °C and + 8 °C. Do not freeze.

Do not use after the expiry date, which is stated on the label of the outer package and the bottle.
Shelf-life after reconstitution: 8-10 hours.

12. SPECIAL WARNING(S)

Special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals

i) Special precautions for use in animals

Handle pregnant females with the usual precautions.

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

To the user:

This product contains mineral oil. Accidental injection /self injection may result in serve pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and the loss of a digit. Expert, prompt, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Use during pregnancy and lactation
The vaccine can be used during pregnancy, and lactation.

Interaction with other medicinal products and others form 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.

Overdose
Administration at 5 times the recommended dose caused, a pink colour of the skin to be observed, which disappeared spontaneously in a few hours.

Major incompatibilities

Do not mix with any other veterinary medicinal product.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

-Box of 1 glass vial (2,5 ml) of 5 doses
-Box of 1 glass vial (5 ml) of 10 doses
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-Box of 1 glass vial (10ml) of 20 doses
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