SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LAPINJECT VHD

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target-species

Rabbit.

4.2 Indications for use

For active immunisation of rabbit to prevent mortality caused by RHD virus

Onset immunity: 6 days
Duration of Immunity: 1 year

4.3 Contra-indications

None.

4.4 Special precautions for use

None

4.5 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 for the person administering the veterinary medicinal product to animals

To the user:
This product contains mineral oil. Accidental injection /self injection may result in severe 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 ischeamic 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.

4.6 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.

4.7 Use during pregnancy and lactation

The vaccine can be used during pregnancy, and lactation.

4.8 Interaction with other medicaments 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 Amount to be administered and administration route

1 dose of 0.5 ml per rabbit, administered subcutaneously.

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

4.10 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. Reactions following administration of an overdose are similar to but larger than those indicated in section 4.6.

4.11 Withdrawal period

Zero days

5. Immunological particulars

To stimulate active immunity against rabbit haemorrhagic disease

ATCvet code: QI08AA01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil
Thiomersal
Sorbitan oleate
Polysorbate 80
Sodium chloride
Potassium chloride
Disodium diphosphate anhydrous
Potassium dihydrate phosphate
Water

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary product as packaged for sale: 2 years
Shelf-life after reconstitution: 8-10 hours.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Nature of the immediate packaging:
. Type I or type II glass vial/bottle
. Stopper of bromobutyl rubber
. Aluminium capsule

Presentations intended for the sale:
- Box of 1 glass vial/bottle (2,5 ml) of 5 doses
- Box of 1 glass vial/bottle (5 ml) of 10 doses
- Box of 10 glass vial/bottle (5 ml) of 10 doses
- Box of 1 glass vial/bottle (10 ml) of 20 doses
- Box of 10 glass vial/bottle (10 ml) of 20 doses
- Box of 1 glass vial/bottle (20 ml) of 40 doses
- Box of 2 glass vial/bottle (20 ml) of 40 doses
- Box of 10 glass vial/bottle (20 ml) of 40 doses
- Box of 1 glass vial/bottle (100 ml) of 200 doses.

6.6 Special precautions for the disposal of unused medicinal 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 the local requirements.

7. NAME OR CORPORATE NAME AND ADDRESS OR REGISTERED PLACE OF BUSINESS OF THE AUTHORIZATION HOLDER

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

8. MARKETING AUTHORISATION NUMBERS

Vm 15052/4032

9. DATE OF FIRST AUTHORISATION

Date: 22 September 2006

10. DATE OF REVISION OF THE TEXT

Date: February 2012