ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Castorex NEO suspension for injection for rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substance:
Inactivated Rabbit Haemorrhagic Disease Virus type 2, strain RHDV2 F/12B min. 0.300 O.D.*

Adjuvant:
Aluminium hydroxide gel max. 1.5 mg

Excipients:
Formaldehyde max. 0.25 mg
Thiomersal max. 0.06mg
For a full list of excipients, see section 6.1.

* ELISA optical density in rabbit sera after vaccination

3. PHARMACEUTICAL FORM

Suspension for injection.
Suspension of red-brown colour with easily shakeable sediment of inactivated RHDV2 adsorbed on aluminium hydroxide gel that forms 40-60% of the vaccine if left undisturbed.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbit.

4.2 Indications for use, specifying the target species

For active immunisation of rabbits to prevent mortality caused by RHD virus type 2.

Onset of immunity: 7 days
Duration of immunity: 1 year

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A slight swelling of 0.5 cm in diameter at the site of injection is uncommon. . Typically, such swelling resolves within 7 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy. The use is not recommended in the last third of gestation in order to avoid stress from handling and risk of abortion. Pregnant does should be handled with special care.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation.

Fertility:
The influence of the vaccination on the fertility of rabbits has not been investigated.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with inactivated RHDV type 1 vaccine (Castorex) in rabbits from 10 weeks of age onwards. The full protection starts at the least 2 weeks after vaccination. The product information of Castorex should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 Amounts to be administered and administration route

The vaccine dose for all age categories is 0.5 ml.

Administer 1 dose of 0.5 ml per rabbit subcutaneously to the lateral thoracic wall according to the following schedule:

Primary vaccination:
1 injection from the age of 6 weeks.
With respect to the epizootological situation, it is possible to vaccinate rabbits from the age of 4 weeks with subsequent booster vaccination 4 weeks after the first injection.

Revaccination:
1 injection every 12 months

Shake well before and occasionally during administration.
Before administration allow warming of vaccine to room temperature.
Administer under usual aseptic conditions using sterile syringes and needles only.

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

No adverse reactions other than already mentioned under section 4.6 can be expected after the administration of a 2-fold vaccine dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccine for rabbits.
ATC vet code: QI08AA01

The vaccine is intended to stimulate active immunity against Rabbit haemorrhagic disease of type 2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel
Formaldehyde
Thiomersal
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 in a refrigerator (2 °C – 8 °C).
Protect from frost. Protect from light.

6.5 Nature and composition of immediate packaging

Paper carton containing glass vial made of neutral borosilicate glass with high hydrolytic resistance (Type 1) closed with a rubber plug suitable for parenteral preparations and an aluminium cap.

Size of package:
10 x 1 dose
1 x 10 doses
1x 20 doses
1x 40 doses

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Name: Pharmagal Bio spol. s r.o.
Address: Murgašova 5, 94901 Nitra
Country: Slovak Republic
Tel./Fax: +421(0) 376533 171
E-mail: bio@pharmagalbio.sk

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

10 DATE OF REVISION OF THE TEXT

MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: 1 x 10 doses, 1 x 20 doses, 1 x 40 doses, 10 x 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Castorex NEO suspension for injection for rabbits

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 mldose contains:
Active substance:
Inactivated Rabbit Haemorrhagic Disease Virus type 2, strain RHDV2 F/12B min. 0.300 O.D.*

* ELISA optical density in rabbit sera after vaccination

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1 x 10 doses
1 x 20 doses
1 x 40 doses
10 x 1 dose

5. TARGET SPECIES

Rabbit

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator .
Protect from frost. Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL BIO spol. s r.o.
Murgašova 5, 94901 Nitra
Slovak Republic

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label on vials: 1 dose, 10, 20 and 40 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Castorex NEO suspension for injection for rabbits

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated Rabbit Haemorrhagic Disease Virus, strain RHDV2 F/12B min. 0.300 O.D.

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

1 dose
10 doses
20 doses
40 doses

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Castorex NEO suspension for injection for rabbits

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

Marketing authorisation holder and manufacturer responsible for batch release:
PHARMAGAL-BIO spol. s r.o.
Murgašova 5
94901 Nitra
Slovak Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Castorex NEO suspension for injection for rabbits

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

Each 0.5 mldose contains:

Active substance:
Inactivated Rabbit Haemorrhagic Disease Virus type2, strain RHDV2 F/12B min. 0.300 O.D.*

Adjuvant:

Aluminium hydroxide gel	max. 1.5 mg

Excipients:

Formaldehyde	max. 0.25 mg
Thiomersal	max. 0.06mg

* ELISA optical density in rabbit sera after vaccination

Suspension of red-brown colour with easily shakeable sediment of inactivated RHDV2 adsorbed on aluminium hydroxide gel that forms 40-60% of the vaccine if left undisturbed.

4. INDICATION(S)

For active immunisation of rabbits to prevent mortality caused by RHD virus type 2.

Onset of immunity: 7 days
Duration of immunity: 1 year

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A slight swelling of 0.5 cm in diameter at the site of injection is uncommon. Typically, such swelling resolves within 7 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).>

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {www.uskvbl.sk}.

7. TARGET SPECIES

Rabbit.

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

The vaccine dose for all age categories is 0.5 ml.

Administer 1 dose of 0.5 ml per rabbit subcutaneously to the lateral thoracic wall according to the following schedule:

Basic vaccination:
1 injection in rabbits from the age of 6 weeks.
With respect to the epizootological situation, it is possible to vaccinate rabbits from the age of 4 weeks with subsequent booster 4 weeks after the first injection.

Revaccination:
1 injection every 12 months

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before and occasionally during administration.
Before administration allow warming of vaccine to room temperature.
Administer under usual aseptic conditions using sterile syringes and needles only.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Protect from frost. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.
Shelf life after first opening the container: 10 hours

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
None

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
Can be used during pregnancy. The use is not recommended in the last third of gestation in order to avoid stress from handling and risk of abortion. Pregnant does should be handled with special care.

Lactation:
The safety of the veterinary medicinal product has not been established during lactation.

Fertility:
The influence of the vaccination on the fertility of rabbits has not been investigated.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with inactivated RHDV type 1 vaccine (Castorex) in rabbits from 10 weeks of age onwards. The full protection starts at the latest 2 weeks after vaccination. The product information of Castorex should be consulted before administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 (symptoms, emergency procedures, antidotes):
No adverse reactions other than already mentioned under section “Adverse reactions” can be expected after the administration of a 2-fold vaccine dose.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Size of package:
1 x 10 doses
1 x 20 doses
1x 40 doses
10 x 1 dose
Not all pack sizes may be marketed.