[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RP Vacc emulsion for injection for pigeons (BE, CZ, DE, NL, PL, PT, RO, SK)
RP Vacc vakcina A. U. V. (HU)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.3 ml dose contains

Active substances:

Pigeon rotavirus, strain Ro/D, inactivated	≥ 52.2 EU*
Pigeon paramyxovirus type 1, strain 988M, inactivated	≥ 6.47 log2 HI**

* ELISA units in chicken
** Haemagglutination inhibition in chicken

Adjuvants:

Paraffin oil	156.9 mg
Sorbitan oleate	15.8 mg
Polysorbate 80	5.7 mg

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	max. 0.036 mg
Formaldehyde	

White emulsion with easily shakeable sediment.

3. CLINICAL INFORMATION

3.1 Target species

Pigeon.

3.2 Indications for use for each target species

For active immunization of pigeons from the age of 4 weeks onwards:

- to reduce frequency and severity of clinical signs, gross lesions and virus shedding caused by pigeon rotavirus group A, genotype G18P[17] (PiRV),
- to reduce mortality, frequency and severity of clinical signs caused by paramyxovirus type 1 (PMV1).

Onset of immunity: 2 weeks after the primary vaccination scheme
Duration of immunity: 8 months (PiRV) / 9 months (PMV1) after the primary vaccination scheme (demonstrated by challenge) for intramuscular injection

For intramuscular administration, in field studies, antibody levels comparable to those demonstrated by the challenge, were found even one year after the last injection.
Duration of immunity has not been established for the subcutaneous route of administration.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
The timing of vaccination/revaccination should be based on risk-benefit assessment of the responsible veterinarian considering the prevalence of particular diseases in breeding and the riskiest periods related to transmission of diseases (i.e. beginning of flying season, exhibition season and/or breeding season).

In the field trial, the presence of maternally derived antibodies against PiRV did not show a negative impact on the development of post-vaccination antibody response.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigeons

Common (1 to 10 animals / 100 animals treated):	Apathy [1] Immediate pain upon injection [2], Injection site swelling [3]

[1] mild apathy one day after vaccination lasting usually up to 1 day after the vaccination
[2] not accompanied by swelling, lasting usually up to 1 day after i.m. administration
[3] up to 0,5 cm in diameter, lasting usually up to 5 days after s.c. administration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products 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.

3.9 Administration routes and dosage

One dose: 0.3 ml
Administer intramuscularly into the femoral muscle or subcutaneously in the dorsal region of the neck towards the tail (not the head).

Primary vaccination scheme:
First dose: from 4 weeks of age onwards
Second dose: 3 weeks later

Revaccination:
Administer one dose one year after last injection at the latest.

In flocks with high PiRV and/or PMV1 infection pressure, it is recommended to revaccinate the pigeons every 8 to 9 months after last injection.

At intramuscular administration of the vaccine, the needle should be inserted at an acute angle, not perpendicular to the site of application.
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.
Use appropriately graduated syringes allowing administration of the exact vaccination dose 0.3 ml.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01EA

The vaccine is intended to stimulate active immunity against pigeon rotavirus group A, genotype G18P[17] (PiRV) and paramyxovirus type 1 (PMV1). The antigens are inactivated with formaldehyde or beta-propiolactone and are adjuvanted with light paraffin oil, sorbitan oleate and polysorbate 80.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 8 hours

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box containing one glass vial, type I closed with chlorobutyl rubber stopper sealed with aluminium cap.
Package size: 1 vial of 50 doses

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

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL-BIO spol. s r.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

cardboard box 1 x 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RP Vacc emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.3 ml dose contains

Pigeon rotavirus, strain Ro/D, inactivated	≥ 52.2 EU*
Pigeon paramyxovirus type 1, strain 988M, inactivated	≥ 6.47 log2 HI**

* ELISA units in chicken
** Haemagglutination inhibition in chicken

3. PACKAGE SIZE

1 x 50 doses

4. TARGET SPECIES

Pigeon

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL-BIO spol. s r.o.

14. MARKETING AUTHORISATION NUMBERS

{Marketing authorisation number}

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RP Vacc emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One 0.3 ml dose contains
Inactivated strains of PiRV ≥ 52.2 EU, PPMV1 ≥ 6.47 log2 HI

3. TARGET SPECIES

Pigeon

4. ROUTES OF ADMINISTRATION

i.m. or s.c. use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL-BIO spol. s r.o.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RP Vacc emulsion for injection for pigeons

2. Composition

Each 0.3 ml dose contains

Active substances:

Pigeon rotavirus, strain Ro/D, inactivated	≥ 52.2 EU*
Pigeon paramyxovirus type 1, strain 988M, inactivated	≥ 6.47 log2 HI**

* ELISA units in chicken
** Haemagglutination inhibition in chicken

Adjuvants:

Paraffin oil	156.9 mg
Sorbitan oleate	15.8 mg
Polysorbate 80	5.7 mg

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	max. 0.036 mg

White emulsion with easily shakeable sediment.

3. Target species

Pigeon

4. Indications for use

For active immunization of pigeons from the age of 4 weeks onwards:

- to reduce frequency and severity of clinical signs, gross lesions and virus shedding caused by pigeon rotavirus group A, genotype G18P[17] (PiRV),
- to reduce mortality, frequency and severity of clinical signs caused by paramyxovirus type 1 (PMV1).

Onset of immunity: 2 weeks after the primary vaccination scheme
Duration of immunity: 8 months (PiRV) / 9 months (PMV1) after the primary vaccination scheme (demonstrated by challenge) for intramuscular administration

For intramuscular administration, in field studies, antibody levels comparable to those demonstrated by the challenge, were found even one year after the last injection.
Duration of immunity has not been established for subcutaneous administration.

5. Contraindications

None.

6. Special warnings

Special precautions for safe use in the target species:
Vaccinate healthy animals only.
The timing of vaccination/revaccination should be based on risk-benefit assessment of the responsible veterinarian considering the prevalence of particular diseases in breeding and the riskiest periods related to transmission of diseases (i.e. beginning of flying season, exhibition season and/or breeding season).

In the field trial, the presence of maternally derived antibodies against PiRV did not show a negative impact on the development of post vaccination antibody response.

Special precautions for use in animals:
Not applicable

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.

To the user:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even 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.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products 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.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable.

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

7. Adverse events

Pigeons

Common	Apathy [1]

(1 to 10 animals / 100 animals treated):	Immediate pain upon injection [2], Injection site swelling [3]

[1] mild apathy one day after vaccination lasting usually up to 1 day after the vaccination
[2] not accompanied by swelling, lasting usually up to 1 day after i.m. administration
[3] up to 0,5 cm in diameter, lasting usually up to 5 days after s.c. administration.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

One dose: 0.3 ml
Administer intramuscularly into the femoral muscle or subcutaneously in the dorsal region of the neck towards the tail (not to the head).

Primary vaccination scheme:
First dose: from 4 weeks of age onwards
Second dose: 3 weeks later

Revaccination:
Administer one dose one year after last injection at the latest.

In flocks with high PiRV and/or PMV1 infection pressure, it is recommended to revaccinate the pigeons every 8 to 9 months after last injection.

9. Advice on correct administration

At intramuscular administration of the vaccine, the needle should be inserted at an acute angle, not perpendicular to the site of application.
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.
Use appropriately graduated syringes allowing administration of the exact vaccination dose 0.3 ml.

10. Withdrawal periods

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 after Exp.
Shelf life after first opening the immediate packaging: 8 hours

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{Marketing authorisation number}
Pack sizes: Cardboard box with one vial of 50 doses

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

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