SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SK, PL, CZ, BE, NL: COLUMBA
DE: COLUMBA PPMV1
HU: COLUMBA vakcina A. U. V

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of the vaccine 0,3 ml contains:
Active substance:
Pigeon paramyxovirus 1 strain 988M-ca, inactivated: inducing ≥ 5.8 log2 HI* and ≤ 12.3 log2 HI units in chickens

* Haemagglutination Inhibition

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigeon.

4.2 Indications for use, specifying the target species

For active immunization of pigeons from the age of 4 weeks onwards to reduce the severity of clinical signs, mortality and excretion period of virus after infection caused by paramyxovirus type 1.

Onset of immunity: 14 days after the last injection
Duration of immunity: 1 year is suggested by serum antibody level recorded

4.3 Contraindications

Do not vaccinate unhealthy birds.

4.4 Special warnings

None.

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 the 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)

Occasionally a slight sweling may be observed at the site of injection for 10 days.
In laboratory studies, small swellings that did not absorb within 28 days after subcutaneous injection in 0,5% of pigeons were observed.

4.7 Use during pregnancy, lactation or lay

No information is available on the use of the vaccine during reproduction period.
Vaccination during the reproduction period is not allowed.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Subcutaneously in the dorsal region of the neck towards the tail, not to the head or intramuscularly into the pectoral muscle. The vaccine dose for each age category of vaccinated animals is 0,3 ml.

Primary vaccination: the first injection from 4 weeks of age onwards
the second injection 21 - 28 days later
Booster: 1 injection every 12 months, at least 21 days before onset of the flying and exhibition season.

Before administration allow to warm to room temperature.
Shake well before and occasionally during administration.
Administer under aseptic conditions.
Only sterile syringes and needles should be used.

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

No undesirable effect has been observed after the administration of several doses except those mentioned in the “Undesirable effects” section.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated viral vaccine, ATCvet code: QI 01EA01

Environmental properties
The virus component is inactivated; thus the spreading among susceptible animals is excluded. The vaccine is administered via injection to individual animal therefore has no direct impact on environment. The inactivated vaccine virus cannot be excreted into the environment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Non-mineral oil emulsion (Montanide ISA 763A VG)
Thiomersal

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: 4 hours or discard.

6.4. Special precautions for storage

Store and transport refrigerated (2 - 8°C). Do not freeze. Protect from light.
It is important to minimize even short-term deviations from the indicated temperature of storage.

6.5 Nature and composition of immediate packaging

9 ml (30 doses), 15 ml (50 doses) or 30 ml (100 doses) glass vials (type I). The vials are closed with chlorobutyl rubber stopper and sealed with aluminium cap.

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 products should be disposed of in accodrance with local requirements.

7. MARKETING AUTHORISATION HOLDER

PHARMAGAL BIO, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic
tel.: +421-37-6533171
fax: +421-37-6533171
email: pharmagalbio@centrum.sk

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

September 2008

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 9 ml vials/15 ml vials/ 30 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SK, PL, CZ, BE, NL: COLUMBA
DE: COLUMBA PPMV1
HU: COLUMBA vakcina A.U.V.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of the vaccine 0,3 ml contains:
Active substance:
Pigeon paramyxovirus 1 strain 988M-ca, inactivated: inducing ≥ 5.8 log2 HI* and ≤ 12.3 log2 HI units in chickens

* Haemagglutination Inhibition

Adjuvant:
Non-mineral oil emulsion
Excipient:
Thiomersal

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

9 ml, 15 ml, 30 ml.

5. TARGET SPECIES

Pigeon.

6. INDICATION(S)

To stimulate active immunity against PPMV-1 infection of pigeons.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 4 hours or discard.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 - 8°C). Do not freeze. Protect from light.
It is important to minimize even short-term deviations from indicated storage temperature.

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

For 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PHARMAGAL BIO, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

9 ml/15 ml/30ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SK, PL, CZ, BE, NL: COLUMBA
DE: COLUMBA PPMV1
HU: COLUMBA vakcina A.U.V.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose of 0,3 ml contains:
Pigeon paramyxovirus 1 strain 988M-ca, inactivated: inducing ≥ 5.8 log2 HI* and ≤ 12.3 log2 HI units in chickens

* Haemagglutination Inhibition

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

9 ml/15 ml/30ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular injection.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 4 hours or discard.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

PACKAGE LEAFLET

SK, PL, CZ, BE, NL: COLUMBA
DE: COLUMBA PPMV 1
HU: COLUMBA vakcina A.U.V.

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:

Pharmagal Bio, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

Manufacturer for the batch release:

Pharmagal Bio, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SK, PL, CZ, BE, NL: COLUMBA
DE: COLUMBA PPMV1
HU: COLUMBA vacina A.U.V.

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

One dose of the vaccine 0,3 ml contains:
Active substance:
Pigeon paramyxovirus 1 strain 988M-ca, inactivated: inducing ≥ 5.8 log2 HI* and ≤ 12.3 log2 HI units in chickens

* Haemagglutination Inhibition

Adjuvant: Non-mineral oil emulsion

Excipients: Thiomersal

4. INDICATION

To stimulate active immunity against PPMV-1 infection of pigeons.
Onset of immunity: 14 days after the last injection
Duration of immunity: 1 year is suggested by serum antibody level recorded

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.

6. ADVERSE REACTIONS

Occasionally a slight sweling may be observed at the site of injection for 10 days.
In laboratory studies, small swellings that did not absorb within 28 days after subcutaneous injection in 0,5% of pigeons were observed.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigeon.

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

The vaccine dose for each age category of vaccinated animals is 0,3 ml.
Subcutaneously in the dorsal region of the neck towards the tail, not to the head or intramuscularly into the pectoral muscle. The vaccine dose for each age category of vaccinated animals is 0,3 ml.

Primary vaccination: the first injection from 4 weeks of age onwards
the second injection 21 - 28 days later
Booster: 1 injection every 12 months, at least 21 days before onset of the flying and exhibition season.

9. ADVICE ON CORRECT ADMINISTRATION

Before administration alow to warm to room temperature.
Shake well before and occasionally during administration.
Administer under aseptic conditions.
Only sterile syringes and needles should be used.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2 - 8°C). Do not freeze. Protect from light.
It is important to minimize even short-term deviations from the indicated temperature of storage.
After broaching use within 4 hours or discard.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

No information is available on the use of the vaccine during reproduction period.
Vaccination during the reproduction period is not allowed.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

Do not mix with any veterinary medicinal product.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED 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 accodrance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED