[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX lyophilisate and solvent for suspension for injection for chickens and turkeys.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.01 ml) contains:

Active substance:
Live attenuated Fowl Pox Virus, strain FPV-92 …….….. $10^{4.0}$ -$10^{4.4}$ EID_{50}*
*Embryo Infective Doses 50%

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: brownish tablet.
Solvent: transparent and colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and turkeys.

4.2 Indications for use, specifying the target species

For active immunization of chickens (broilers and future layers and breeders) and turkeys to reduce clinical signs after infection with Fowl Pox Virus.
Onset of immunity: 21 days after vaccination.
Duration of immunity is not established.

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
Apply carefully the vaccine by wing-web-stab use in a manner that does not provoke lesions in the blood vessels.

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)

Very common adverse reactions:
By days 7 to 10 post-vaccination one or two nodules at the inoculation site of all vaccinated animals, which become scabs were observed in safety studies; they are a sign that vaccination has taken. Those scabs will disappear by 2 to 3 weeks post-vaccination.

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

Do not use in birds in lay and within 4 weeks before the start of the laying period.

4.8 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.

4.9 Amounts to be administered and administration route

Do not dissolve the freeze dried tablet in the solvent if it is at a temperature above 25 ºC.

The posology is 1 dose (0.01 ml)/bird.

For the preparation of the vaccine, peel the aluminium capsule off the vial containing the solvent, insert a syringe with hypodermic needle and aspirate in order to remove a certain volume of the content. Then inject this volume of solvent into the vial with the lyophilized vaccine. Shake until the tablet is completely dissolved. Once reconstituted, withdraw all the suspension obtained and inject in the vial containing the remaining solvent. Shake well to obtain a homogeneous suspension. Finally, completely immerse the scarifier in the vaccine preparation. The final administration depends on whether the vaccine is administered to chickens or to turkeys.

Routes of administration: Wing-web-stab use (chickens) and skin scarification (turkeys).

Chickens: Once the scarifier has been immersed into the vaccine preparation, extend the wing membrane and apply carefully the vaccine by wing-web-stab in a manner that does not provoke lesions in the blood vessels. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Turkeys: Once the scarifier has been immersed into the vaccine preparation one drop of vaccine suspension will be applied by skin scarification on the thigh. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Vaccination schedule:
- Broilers: vaccinated from one day of age.
- Future layers and breeders: vaccinate between 8 and 12 weeks of age. In areas at high risk for the disease, birds can be vaccinated from one day of age and revaccinated before lay.
- Turkeys: vaccinated from one day of age.

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

Administering a ten-fold dose of that recommended does not produce adverse effects other than those mentioned in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Avian pox virus.
ATC vet code: QI01AD12.

To stimulate active immunity against infection with Fowl Pox Virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Povidone
Sucrose
Sodium glutamate

Solvent:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

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 dilution or reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Lyophilisate: store and transport refrigerated (2 °C – 8 °C). Protect from light. Do not freeze.
Solvent: do not store above 25 ºC. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Containers for the lyophilisate and for the solvent: 10 ml Type I, neutral glass vials; Type I bromobutyl rubber closures and aluminium cap.

Cardboard box with 5 vials of 1,000 doses of lyophilisate and 5 vials of 10 ml of solvent for reconstitution of 1,000 doses.
A double-bladed nickel-plated steel scarifier with plastic handle is also included.

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

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 430660
Fax +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.
Date of last renewal: {DD/MM/YYYY}.

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Dispensation conditions: Medicament by veterinary prescription.
Administration conditions: Administration under veterinary control or supervision.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX FOR THE LYOPHILISATE AND SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX lyophilisate and solvent for suspension for injection for chickens and turkeys.

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (0.01 ml) contains:

Active substance:
Live attenuated, Fowl Pox Virus, strain FPV-92 …….….. $10^{4.0}$-$10^{4.4}$ EID_{50}*
*Embryo Infective Dose 50%

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

5 vials of 1000 doses of lyophilisate and 5 vials of 10 ml of solvent for reconstitution of 1000 doses.

5. TARGET SPECIES

Chickens and turkeys.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Wing-web-stab use (chickens).
Skin scarification (turkeys).
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

12. SPECIAL 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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 43 06 60
Fax +34 972 43 06 61
E-mail: hipra@hipra.com

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABELS FOR GLASS VIALS OF LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX lyophilisate and solvent for suspension for injection for chickens and turkeys.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (0.01 ml) contains:

Active substance:
Live attenuated, Fowl Pox Virus, strain FPV-92 …….….. $10^{4.0}$-$10^{4.4}$ EID_{50}*
*Embryo Infective Dose 50%

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

1000 doses

4. ROUTE(S) OF ADMINISTRATION

Wing-web-stab use (chickens)
Skin scarification (turkeys)

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX (solvent)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

10 ml of solvent for reconstitution of 1000 doses

4. ROUTE(S) OF ADMINISTRATION

The posology is 1 dose (0.01 ml)/bird.
Route of administration: wing-web-stab use (chickens) and skin scarification (turkeys).

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

<Batch><Lot> {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HIPRAPOX
Lyophilisate and solvent for suspension for injection for chickens and turkeys.

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:
Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAPOX
Lyophilisate and solvent for suspension for injection for chickens and turkeys.

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

One dose (0.01 ml) contains:

Active substance: Live attenuated, Fowl Pox Virus, strain FPV-92 ……..….. $10^{4.0}$-$10^{4.4}$ EID_{50}*
*Embryo Infective Dose 50%

Lyophilisate: brownish tablet.
Solvent: transparent and colourless solution.

4. INDICATION(S)

For active immunization of chickens (broilers and future layers and breeders) and turkeys to reduce clinical signs after infection with Fowl Pox Virus.
Onset of immunity: 21 days after vaccination.
Duration of immunity is not established.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very common adverse reactions:
By days 7 to 10 post-vaccination one or two nodules at the inoculation site of all vaccinated animals, which become scabs were observed in safety studies; they are a sign that vaccination has taken. Those scabs will disappear by 2 to 3 weeks post-vaccination.

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.

7. TARGET SPECIES

Chickens and turkeys.

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

Do not dissolve the freeze dried tablet in the solvent if it is at a temperature above 25 ºC.

The posology is 1 dose (0.01 ml)/bird.

The administration of the vaccine is by wing-web-stab use in chickens and by skin scarification in the thigh in turkeys.

Chickens: extend the wing membrane and administer carefully the vaccine by wing-web-stab use in a manner that does not provoke lesions in the blood vessels. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Turkeys: administer one drop of vaccine suspension that will be applied by skin scarification on the thigh. The scarifier must be freshly impregnated with the vaccine suspension to perform each administration.

Vaccination schedule:
- Broilers: vaccinated from one day of age.
- Future layers and breeders: vaccinate between 8 and 12 weeks of age. In areas at high risk for the disease, birds can be vaccinated from one day of age and revaccinated before lay.
- Turkeys: vaccinated from one day of age.

9. ADVICE ON CORRECT ADMINISTRATION

For the preparation of the vaccine, peel the aluminium capsule off the vial containing the solvent, insert a syringe with hypodermic needle and aspirate in order to remove a certain volume of the content. Then inject this volume of solvent into the vial with the lyophilized vaccine. Shake until the tablet is completely dissolved. Once reconstituted, withdraw all the suspension obtained and inject in the vial containing the remaining solvent. Shake well to obtain a homogeneous suspension. Finally, completely immerse the scarifier in the vaccine preparation. The final administration depends on whether the vaccine is administered to chickens or to turkeys.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate:
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

Solvent:
Do not store above 25 ºC.
Protect from light.
Do not freeze.

Shelf life after dilution or reconstitution according to directions: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
The vaccine should be applied carefully by wing-web-stab use in a manner that does not provoke lesions in the blood vessels.

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.

Use during gestation, lactation or lay:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

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):
Administering a ten-fold dose of that recommended does not produce adverse effects other than those mentioned in point 6.

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

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

Cardboard box with 5 vials of 1,000 doses of lyophilisate and 5 vials of 10 ml of solvent for reconstitution of 1,000 doses.
A double-bladed nickel-plated steel scarifier with a plastic handle is included.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.