ANNEXE I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dindoral lyophilisate for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Attenuated avian Adenovirus group II, Domermuth strain QS: 9/10 seroconversions*

* One seroconversion must be obtained on at least 9 SPF chickens aged 2-3 weeks out of 10 vaccinated (ELISA test).

Excipients:

Qualitative composition of excipients and other constituents
Skimmed milk
Sodium Glutamate
Water for injection

Lyophilisate: dark freeze-dried pellet

3. CLINICAL INFORMATION

3.1 Target species

Turkeys and pheasants.

3.2 Indication for use for each target species

In turkeys from the age of 4 weeks: active: immunisation against the haemorrhagic enteritis.
Onset of immunity: 7 days.
Duration of immunity: 7 weeks after the onset of immunity.

In pheasant from the age of 4 weeks: active immunisation against the marble spleen disease.
The onset and duration of immunity are not established.

3.3 Contraindications

Do not administer to young guinea fowls.
Do not vaccinate breeders and future breeders.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccine virus can spread to unvaccinated birds. Infection of unvaccinated turkeys with the vaccine virus from vaccinated birds does not cause any signs of disease.
Vaccinate all of the turkeys in a farm at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after vaccinating.
The vaccine strain is shed by vaccinated birds. Personnel involved in attending vaccinated turkeys and pheasants should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated turkeys and pheasants.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Turkeys:
After vaccination, a temporary reduction of humoral immunity was observed in SPF turkey poults, and a significant and brief lymphocyte depletion in conventional turkey poult. The biological significance of these properties is not established.

Pheasants:
No known adverse events.

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 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

Laying birds:
Do not use in birds in lay.

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

Turkey poults and pheasant poults: one administration as from the age of 4 weeks.

To use the vaccine, push in the needle of a syringe pre-filled with drinking water through the vial cap. Inject the water, take the reconstituted vaccine after complete dissolution with the syringe and put its contents in the container containing the drinking water volume necessary to administer the product. Then rinse the vial twice and add the rinsing liquid to the drinking water.

Drinking water (oral route): For 1 000 birds, reconstitute the 1 000-dose lyophilisate in 1 ml of drinking water, then dilute it in the amount of drinking water normally absorbed within one to two hours. Give the vaccine solution to birds deprived of drinking water for two hours.

Appearance after reconstitution: homogeneous milky white.

Use clean and disinfectant or antiseptic-free materials for the preparation of the vaccine solution.

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

No undesirable effects were observed following the administration of 10 doses in pheasants.

In the SPF turkey poults, the weight gain can be slightly reduced following the administration of a 10-fold overdose.

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 NFORMATION

4.1 ATCvet code: QI01CD

Avian immunological product, turkey, live viral vaccines.
The vaccine induces active immunity against turkey hemorrhagic enteritis and marbled spleen disease in pheasants.

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 reconstitution according to directions: use within 3 hours at room temperature.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass bottle
Butyl elastomer closure
Aluminium cap

Box of 1 bottle of 500 doses
Box of 1 bottle of 1 000 doses
Box of 1 bottle of 5 000 doses
Box of 10 bottles of 1 000 doses
Box of 10 bottles of 5 000 doses

Not all pack sizes may be marketed.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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*).

ANNEXE III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULAR TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 500 or 1 000 or 5 000 doses
Box of 10 bottles of 1 000 or 5 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dindoral lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Attenuated avian Adenovirus group II, Domermuth strain QS: 9/10 seroconversions

3. PACKAGE SIZE

1 x 500 doses
1 x 1 000 doses
1 x 5 000 doses
10 x 1 000 doses
10 x 5 000 doses

4. TARGET SPECIES

Turkeys and pheasants

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 3 hours at room temperature.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

Boehringer Ingelheim

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass bottle of 5 ml or 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dindoral

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Attenuated avian Adenovirus group II, Domermuth strain

500 doses
1 000 doses
5 000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 3 hours at room temperature.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dindoral lyophilisate for use in drinking water

2. Composition

Active substance:
Attenuated avian Adenovirus group II, Domermuth strain QS: 9/10 seroconversions*

* One seroconversion must be obtained on at least 9 SPF chickens aged 2-3 weeks, out of 10 vaccinated (ELISA test).

Excipient: qs. 1 dose.

Lyophilisate: dark freeze-dried pellet.

3. Target species

Turkeys and pheasants.

4. Indications for use

In turkeys from the age of 4 weeks: active: immunisation against the haemorrhagic enteritis.
Onset of immunity: 7 days.
Duration of immunity: 7 weeks after the onset of immunity.

In pheasants from the age of 4 weeks: active immunisation against the marble spleen disease.
The onset and duration of immunity are not established.

5. Contraindications

Do not administer to young guinea fowls.
Do not vaccinate breeders and future breeders.

6. Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Vaccine virus can spread to unvaccinated birds. Infection of unvaccinated turkeys with the vaccine virus from vaccinated birds does not cause any signs of disease
Vaccinate all the turkeys in a farm at the same time.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after vaccinating.
The vaccine strain is shed by vaccinated birds. Personnel involved in attending vaccinated turkeys and pheasants should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated turkeys and pheasants.

Laying birds:
Do not use in birds in lay.

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:
No undesirable effects were observed following the administration of 10 doses in pheasants.
In the SPF turkey poults, the weight gain can be slightly reduced following the administration of a 10-fold overdose.

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

7. Adverse events

Turkeys:
After vaccination, a temporary reduction of humoral immunity was observed in SPF turkey-poults, and a significant and brief lymphocyte depletion in conventional turkey-poult. The biological significance of these properties is not established.

Pheasants:
No known adverse events.

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 using the contact details at the end of this leaflet, or via your national reporting system.

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

Turkey poults and pheasant poults: one administration as from the age of 4 weeks.

To use the vaccine, push in the needle of a syringe filled with drinking water through the vial cap. Inject the water, take the reconstituted vaccine after complete dissolution with the syringe and put its contents in the container containing the drinking water volume necessary to administer the product. Then rinse the vial twice and add the rinsing liquid to the drinking water.

Drinking water (oral route): For 1 000 birds, reconstitute the 1 000-dose lyophilisate in 1 ml of drinking water, then dilute it in the amount of drinking water normally absorbed within one to two hours. Give the vaccine solution to birds deprived of drinking water for two hours.

Appearance after reconstitution: homogeneous milky white.

9. Advice on correct administration

Use clean and disinfectant or antiseptic-free materials for the preparation of the vaccine solution.

10. Withdrawal periods:

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp.
Shelf life after reconstitution according to directions: use within 3 hours at room temperature.

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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Box of 1 bottle of 500 doses
Box of 1 bottle of 1 000 doses
Box of 10 bottles of 1 000 doses
Box of 1 bottle of 5 000 doses
Box of 10 bottles of 5 000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse reactions:

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation

69800 Saint-Priest
France