ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXINACT H5 emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose of vaccine contains:

Active substances:
Avian influenza virus, subtype H5, haemagglutinin (recombinant), at least.....256 HAU*
**HAU: haemagglutination units*

Adjuvants:
Light paraffin oil .....275.5 mg
Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan oleate
Water for injections

Homogenous white emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Chickens, ducks (Mulard, Pekin and Muscovy), and turkeys.

3.2 Indications for use for each target species

Chickens:

Active immunisation of chickens from 10 days of age to prevent mortality, clinical signs and reduce viral excretion associated with highly pathogenic avian influenza (HPAI) infection related to H5, including the circulating clade 2.3.4.4b.

For use in chickens either as a single dose from 10 days of age (for example, in broilers) or as a booster vaccine in a prime-boost vaccination scheme (for example, in layers and breeders). See section 3.9 of the summary of product characteristics.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 6 weeks after vaccination (without priming with a vHVT-H5 vaccine) or 12 weeks after vaccination (with priming with a vHVT-H5 vaccine).

Ducks:

Mulard
Active immunisation of Mulard ducks from 1 day of age or older to prevent mortality, clinical signs and reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 14 days after vaccination.

Duration of immunity: 9 weeks after vaccination.

Pekin
Active immunisation of Pekin ducks from 1 day of age or older to reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 7 weeks after vaccination.

Muscovy
Active immunisation of Muscovy ducks from 1 day of age or older to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 7 weeks after vaccination.

Turkeys:
Active immunisation of turkeys from 28 days of age, after priming with a vHVT-H5 vaccine, to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 9 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Chickens: the presence of HPAI H5 maternally derived antibodies on vaccine efficacy has not been fully investigated in accordance with requirements, however available data would suggest that maternally derived antibodies may reduce vaccine efficacy.
Ducks and turkeys: the impact of the presence of HPAI H5 maternally derived antibodies on vaccine efficacy has not been established in ducks or turkeys.

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:

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

Chickens:

Very common (> 1 animal / 10 animals treated):	Injection site reaction

Ducks:

Very common (> 1 animal / 10 animals treated):	Injection site swelling[1,2], injection site reddening[2], injection site crust[2]

[1] Mulard ducks: resolving within 2 days.
[2] Muscovy ducks: maximum size of 2.5 cm, resolving within 7 days (swelling and reddening), or 15 days (crust).

Turkeys:

Very common (> 1 animal / 10 animals treated):	Injection site swelling[3], injection site reddening[3], injection site mass[3], injection site thickening[3]

[3] Maximum size of 1.5 cm, resolving within 7 days.

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.

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

Subcutaneous use.

The vaccine should be taken out of the refrigerator and allowed to reach room temperature before use.

Dose: 0.5 ml per bird.
Subcutaneous injection, median third of neck.

Chickens:

Chickens from 10 days of age and older (broilers, layer and breeder chickens):
Single dose vaccination scheme: Give one dose of 0.5 ml per bird.
Prime-boost vaccination scheme: Give one dose of 0.5 ml per bird after priming from 1 day of age with a vHVT-H5 vaccine. The interval between prime and boost is recommended as 12 weeks.

Ducks:

Ducks (Pekin and Muscovy) 1 day of age and older: Give one dose of 0.5 ml per bird and a second dose of 0.5 ml 21 days later.

Ducks (Mulard) 1 day of age and older: Give one dose of 0.5 ml per bird and a second dose of 0.5 ml 28 days later.

Turkeys:

Turkeys 28 days of age and older: Give one dose of 0.5 ml per bird after priming with a vHVT-H5 vaccine from 1 day of age. The interval between prime and boost should be no less than 28 days.

Shake well before and during use.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Equipment including needles and syringes must be sterile before use.

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

No other signs than those reported in section "Adverse events" were observed in chickens after the administration of a 2x dose. The safety of an overdose has not been established in ducks and turkeys.

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

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA23.

Inactivated subunit vaccine containing haemagglutinin H5 of Avian Influenza virus H5N1 strain produced on the Baculovirus Expression System Technology (B.E.S.T.).

Vaccination does not induce production of antibodies against nucleoprotein or neuraminidase, and therefore a DIVA (Differentiation of Infected from Vaccinated Animals) strategy can be implemented.

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: 18 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

500 ml (1 000 doses) high density polyethylene bottle with a nitrile closure sealed with aluminium cap.
Each carton box contains 20 bottles.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/356/001

8. DATE OF FIRST AUTHORISATION

04/12/2025

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

DD/MM/YYYY

EXCEPTIONAL CIRCUMSTANCES:
Marketing authorisation in exceptional circumstances and therefore assessment based on customised requirements for documentation. Only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive quality, safety or efficacy data.

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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION IN EXCEPTIONAL CIRCUMSTANCES

This being an approval in exceptional circumstances and pursuant to Article 25 of Regulation (EU) 2019/6, the MAH shall conduct, within the stated timeframe, the following measures:

Description	Due date
The results of real time stability studies for the active substance, up to 15 months, should be provided for at least 2 batches to confirm the 15-months shelf-life assigned. Any out of specification results or adverse trends should be communicated immediately to the European Medicines Agency.	April 2026
The results of real time stability studies for the vaccine, up to 21 months (including sterility results), should be provided for at least 2 batches to confirm the 18-months shelf-life assigned. Any out of specification results or adverse trends should be communicated immediately to the European Medicines Agency.	July 2026

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box, Bottle of 500 ml (1 000 doses) x 20

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXINACT H5 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml dose contains:

Avian influenza virus, subtype H5, haemagglutinin (recombinant), at least..... 256 HAU

3. PACKAGE SIZE

20 x 500 ml (20 x 1 000 doses)

4. TARGET SPECIES

Chickens, ducks (Mulard, Pekin and Muscovy), and turkeys.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

s.c.
Shake well before use.

7. WITHDRAWAL PERIODS

Withdrawal periods: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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”

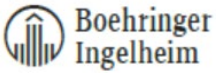
For animal treatment only.

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 Vetmedica GmbH



14. MARKETING AUTHORISATION NUMBERS

EU/2/25/356/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1 000 dose bottle, 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VAXXINACT H5 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per 0.5 ml dose:
Avian influenza virus, subtype H5, haemagglutinin (recombinant), at least..... 256 HAU

500 ml

3. TARGET SPECIES

Chickens, ducks (Mulard, Pekin and Muscovy), and turkeys.

4. ROUTES OF ADMINISTRATION

s.c.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

VAXXINACT H5 emulsion for injection

2. Composition

Each 0.5 ml dose of vaccine contains:

Active substances:
Avian influenza virus, subtype H5, haemagglutinin (recombinant), at least.....256 HAU*
**HAU: haemagglutination units*

Adjuvants:
Light paraffin oil .....275.5 mg

Homogeneous white emulsion after shaking.

3. Target species

Chickens, ducks (Mulard, Pekin and Muscovy), and turkeys.

4. Indications for use

Chickens:
Active immunisation of chickens from 10 days of age to prevent mortality, clinical signs and reduce viral excretion associated with highly pathogenic avian influenza (HPAI) infection related to H5 including the circulating clade 2.3.4.4b.

For use in chickens either as a single dose from 10 days of age (for example, in broilers) or as a booster vaccine in a prime-boost vaccination scheme (for example, in layers and breeders). See "Dosage for each species, routes and method of administration" section.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 6 weeks after vaccination (without priming with a vHVT-H5 vaccine) or 12 weeks after vaccination (with priming with a vHVT-H5 vaccine).

Ducks:

Mulard
Active immunisation of Mulard ducks from 1 day of age or older to prevent mortality, clinical signs and reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 14 days after vaccination.
Duration of immunity: 9 weeks after vaccination.

Pekin
Active immunisation of Pekin ducks from 1 day of age or older to reduce viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.

Duration of immunity: 7 weeks after vaccination.

Muscovy
Active immunisation of Muscovy ducks from 1 day of age or older to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 7 weeks after vaccination.

Turkeys:
Active immunisation of turkeys from 28 days s of age, after priming with a vHVT-H5 vaccine, to reduce mortality, clinical signs and viral excretion associated with HPAI infection related to H5, including the circulating clade 2.3.4.4b.

Onset of immunity: 21 days after vaccination.
Duration of immunity: 9 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
Chickens: the presence of HPAI H5 maternally derived antibodies on vaccine efficacy has not been fully investigated in accordance with requirements, however available data would suggest that maternally derived antibodies may reduce vaccine efficacy.
Ducks and turkeys: the impact of the presence of HPAI H5 maternally derived antibodies on vaccine efficacy has not been established in ducks or turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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.

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 other signs than those reported in section "Adverse events" were observed in chickens after the administration of a 2x dose. The safety of an overdose has not been established in ducks and turkeys.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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

7. Adverse events

Chickens:
Very common (> 1 animal / 10 animals treated): Injection site reaction.

Ducks:
Very common (> 1 animal / 10 animals treated): Injection site swelling[1,2], injection site reddening[2], injection site crust[2].

[1] Mulard ducks: resolving within 2 days.
[2] Muscovy ducks: maximum size of 2.5 cm, resolving within 7 days (swelling and reddening), or 15 days (crust).

Turkeys:
Very common (> 1 animal / 10 animals treated): Injection site swelling[3], injection site reddening[3], injection site mass[3], injection site thickening[3].

[3] Maximum size of 1.5 cm, resolving within 7 days.

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 its local representative 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

Subcutaneous use (s.c.).
The vaccine should be taken out of the refrigerator and allowed to reach room temperature before use.

Dose: 0.5 ml per bird.
Subcutaneous injection, median third of neck.

Chickens:
Chickens from 10 days of age and older (broilers, layer and breeder chickens):
Single dose vaccination scheme: Give one dose of 0.5 ml per bird.

Prime-boost vaccination scheme: Give one dose of 0.5 ml per bird after priming from 1 day of age with a vHVT-H5 vaccine. The interval between prime and boost is recommended as 12 weeks.

Ducks:
Ducks (Pekin and Muscovy) 1 day of age and older: Give one dose of 0.5 ml per bird and a second dose of 0.5 ml 21 days later.
Ducks (Mulard) 1 day of age and older: Give one dose of 0.5 ml per bird and a second dose of 0.5 ml 28 days later.

Turkeys:
Turkeys 28 days of age and older: Give one dose of 0.5 ml per bird after priming with a vHVT-H5 vaccine from 1 day of age. The interval between prime and boost should be no less than 28 days.

9. Advice on correct administration

Shake well before and during use.
Apply usual aseptic procedures.
Do not use syringes with natural rubber or butyl elastomer pistons.
Equipment including needles and syringes must be sterile before use.

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 freeze.

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: use immediately.

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

EU/2/25/356/001

500 ml (1 000 dose) bottle, carton box of 20 bottles.

15. Date on which the package leaflet was last revised

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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health Italia S.p.A
Via Baviera, 9
35027 Noventa Padovana
Italia

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
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17. Other information

Inactivated subunit vaccine containing haemagglutinin H5 of Avian Influenza virus H5N1 strain produced on the Baculovirus Expression System Technology (B.E.S.T.).

Vaccination does not induce production of antibodies against nucleoprotein or neuraminidase, and therefore a DIVA (Differentiation of Infected from Vaccinated Animals) strategy can be implemented.