ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Procerta HVT-IBD concentrate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.05 ml or 0.2 ml) contains:

Active substance:

Turkey herpes virus, strain HVT-IBD (cell-associated), expressing VP2 protein gene of infectious bursal disease virus, live: 3580 - 26500 PFU*.

*PFU: plaque forming units.

Excipients:

Qualitative composition of excipients and other constituents
Concentrate:
Dimethyl sulfoxide
Bovine calf serum
L-glutamine
DMEM
Solvent:
Sucrose
Potassium dihydrogen phosphate
Dipotassium phosphate
Peptone (NZ Amine)
Phenol red
Water for injections

Concentrate: light orange to light pink concentrate.
Solvent: clear red liquid.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and embryonated chicken eggs.

3.2 Indications for use for each target species

For active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to
- reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus and
- prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease (IBD) virus.

Onset of immunity: MD: 7 days post vaccination for *in ovo* and 9 days for subcutaneous use

IBD: 15 days post vaccination for *in ovo* and 12 days for subcutaneous use

Duration of immunity: MD: a single vaccination is sufficient to provide protection for the entire risk period
IBD: 64 days of age

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine strain may be excreted by vaccinated chickens for a maximum of 6 weeks post-vaccination and has the potential to spread to turkeys and to a very limited extent to chickens. Safety trials (including reversion to virulence studies in chickens) have shown that the strain is safe for turkeys and chickens. However, precautionary measures including following general hygiene principles and taking particular care in handling animal waste and bedding materials from recently vaccinated chickens should be taken to avoid spreading of the vaccine strain.

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

Liquid nitrogen can cause serious freeze burns and thawing ampoules may occasionally explode as result of sudden temperature changes. Therefore, liquid nitrogen containers and vaccine ampoules should be handled by properly trained personnel only.

Personal protective equipment consisting of gloves, facial protection or safety goggles and skin-covering clothing should be worn when handling the veterinary medicinal product starting when withdrawing from liquid nitrogen.

Store and use liquid nitrogen only in a dry and well-ventilated place.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens and embryonated chicken eggs:

None known.

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

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

The vaccine is administered to chickens by subcutaneous injection in the neck or by *in ovo* injection.

One single injection of 0.2 ml per chicken at day of hatch, by subcutaneous use.
One single injection of 0.05 ml per chicken egg at 18-19 days of embryonation, by *in ovo* route.

Preparation of the vaccine:
Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane. Special care has to be taken to ensure that mix-ups of ampoules with different number of doses is avoided and the correct volume of solvent (Poulvac Solvent) is used.

For subcutaneous use, reconstitute each 2,000 doses with 400 ml of Poulvac Solvent and each 4,000 doses with 800 ml of Poulvac Solvent. For *in ovo* use, reconstitute each 2,000 doses with 100 ml of Poulvac Solvent and 4,000 doses with 200 ml of Poulvac Solvent. The solvent must be at room temperature (15 °C – 25 °C) at the time of mixing with the vaccine.

Overview tables for the dilution examples for the different dose presentations for both subcutaneous and *in ovo* administration are provided:

Poulvac Solvent bag	**Number of vaccine ampoules for subcutaneous use**
Bag of 400 ml solvent	1 ampoule containing 2,000 doses
Bag of 800 ml solvent	2 ampoules containing 2,000 doses
Bag of 800 ml solvent	1 ampoule containing 4,000 doses

Poulvac Solvent bag	**Number of vaccine ampoules for *in ovo* use**
Bag of 200 ml solvent	2 ampoules containing 2,000 doses
Bag of 400 ml solvent	4 ampoules containing 2,000 doses
Bag of 400 ml solvent	2 ampoules containing 4,000 doses
Bag of 800 ml solvent	4 ampoules containing 4,000 doses
Bag of 1,000 ml solvent	5 ampoules containing 4,000 doses

Reconstitution should be done under aseptic conditions. Before withdrawing the ampoules from the liquid nitrogen container, protect the hands with gloves, wear long sleeves and use a face shield or goggles.

It is recommended to handle a maximum of 5 ampoules at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.

Take the ampoule(s) of vaccine out of the liquid nitrogen container and thaw the vaccine by immersing in water at 25 ºC – 30 ºC, while gently swirling the ampoule(s) to disperse the content. As soon as vaccine in the ampoule is completely thawed, remove from the water, dry the ampoule and break the ampoules at its neck.

Once opened, slowly withdraw the total contents of the ampoule carefully into a 10 ml sterile disposable syringe with an 18-gauge needle. Slowly draw about 8 ml of Poulvac Solvent into the syringe. Turn the syringe 5-10 times to mix the contents well. Slowly transfer a small volume of the mixture into the empty vaccine ampoule in order to rinse the ampoule and withdraw this small amount back into the syringe.

Carefully transfer the entire content of the syringe into the Poulvac Solvent container. Remove the syringe and invert the solvent bag about 10 times to mix the vaccine. The vaccine is now ready for use.

The ready to use vaccine is a red, slightly opalescent liquid.

In case automated equipment is used for *in ovo* or subcutaneous administration, the equipment should be calibrated to ensure that the correct dose is applied to each egg or chicken. The instructions for use of this device should be followed.

The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered.

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

No symptoms were observed after the administration of a 10-fold dose of the vaccine.

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: QI01AD15

The vaccine contains a cell-associated live recombinant turkey herpesvirus (HVT) expressing the VP2 protein of infectious bursal disease virus. The vaccine induces active immunity against infectious bursal disease (Gumboro disease) and Marek's disease in chickens.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product except solvent recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life of the solvent (Poulvac Solvent) as packaged for sale: 2 years.
Shelf life after dilution according to directions: 2 hours.

5.3 Special precautions for storage

Concentrate:
Store and transport frozen in liquid nitrogen (or vapour phase) at or below -150 °C.

Poulvac Solvent:
Store at or below 25 °C. Protect from light.

5.4 Nature and composition of immediate packaging

Concentrate:
Type I glass ampoule containing 2,000 or 4,000 doses of the vaccine.
The ampoules are stored in cryopreservation containers in a cane. The dose presentation is presented on the extremity of each cane.

Poulvac Solvent:
Polyvinylchloride (PVC) and polypropylene plastic bag containing 200 ml, 400 ml, 800 ml, and 1,000 ml.
The solvent is packed separately from the ampoules.

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

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/300/001 (2000 doses)
EU/2/23/300/002 (4000 doses)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 26/10/2023.

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

{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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

2,000 DS AMPOULES
4,000 DS AMPOULES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Procerta HVT-IBD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

HVT-IBD

2000
4000
(number of doses per ampoule is presented on the colour coded clip attached to each cane containing the ampoule and not on the ampoule)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

(IMMEDIATE) SOLVENT BAG OF 200 ML; 400 ML; 800 ML; 1,000 ML

1. NAME OF THE DILUENT

Poulvac Solvent

200 ml
400 ml
800 ml
1,000 ml

2. TARGET SPECIES

Chickens

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine before use.

4. EXPIRY DATE

Exp. {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store at or below 25 °C.
Protect from light.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Company logo

7. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Poulvac Procerta HVT-IBD concentrate and solvent for suspension for injection for chickens

2. Composition

Each dose (0.05 ml or 0.2 ml) contains:

Active substance:

Turkey herpes virus, strain HVT-IBD (cell-associated), expressing VP2 protein gene of infectious bursal disease virus, live: 3580 - 26500 PFU*.

*PFU: plaque forming units.

Concentrate: light orange to light pink concentrate.
Solvent: clear red liquid.

3. Target species

Chickens and embryonated chicken eggs.

4. Indications for use

For active immunisation of one day old chickens and 18-19 day old embryonated chicken eggs to
- reduce mortality, clinical signs and lesions caused by Marek's disease (MD) virus and
- prevent mortality and clinical signs and reduce lesions caused by infectious bursal disease (IBD) virus.

Onset of immunity:	MD: 7 days post vaccination for *in ovo* and 9 days for subcutaneous use IBD: 15 days post vaccination for *in ovo* and 12 days for subcutaneous use
Duration of immunity:	MD: a single vaccination is sufficient to provide protection for the entire risk period IBD: 64 days of age

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The vaccine strain may be excreted by vaccinated chickens for a maximum of 6 weeks post-vaccination and has the potential to spread to turkeys and to a very limited extent to chickens. Safety trials (including reversion to virulence studies in chickens) have shown that the strain is safe for turkeys and chickens. However, precautionary measures including following general hygiene

principles and taking particular care in handling animal waste and bedding materials from recently vaccinated chickens should be taken to avoid spreading of the vaccine strain.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Liquid nitrogen can cause serious freeze burns and thawing ampoules may occasionally explode as result of sudden temperature changes. Therefore, liquid nitrogen containers and vaccine ampoules should be handled by properly trained personnel only.
Personal protective equipment consisting of gloves, facial protection or safety goggles and skin-covering clothing should be worn when handling the veterinary medicinal product starting when withdrawing from liquid nitrogen.
Store and use liquid nitrogen only in a dry and well-ventilated place.

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

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 symptoms were observed after the administration of a 10-fold dose of the vaccine.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except solvent recommended for use with the veterinary medicinal product.

7. Adverse events

Chickens and embryonated chicken eggs:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, 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: {national system details}.

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

The vaccine is administered to chickens by subcutaneous injection in the neck or by *in ovo* injection.

One single injection of 0.2 ml per chicken at day of hatch, by subcutaneous use.
One single injection of 0.05 ml per chicken egg at 18-19 days of embryonation, by *in ovo* route.

Preparation of the vaccine:

Preparation of the vaccine shall be planned before the ampoules are taken from the liquid nitrogen and the exact amount of vaccine ampoules and amount of solvent needed shall be calculated first. There is no information available on the number of doses on the ampoules once they are removed from the cane. Special care has to be taken to ensure that mix-ups of ampoules with different number of doses is avoided and the correct volume of solvent (Poulvac Solvent) is used.

For subcutaneous use, reconstitute each 2,000 doses with 400 ml of Poulvac Solvent and each 4,000 doses with 800 ml of Poulvac Solvent. For *in ovo* use, reconstitute each 2,000 doses with 100 ml of Poulvac Solvent and 4,000 doses with 200 ml of Poulvac Solvent. The solvent must be at room temperature (15 °C – 25 °C) at the time of mixing with the vaccine.

Overview tables for the dilution examples for the different dose presentations for both subcutaneous and *in ovo* administration are provided:

Poulvac Solvent bag	**Number of vaccine ampoules for subcutaneous use**
Bag of 400 ml solvent	1 ampoule containing 2,000 doses
Bag of 800 ml solvent	2 ampoules containing 2,000 doses
Bag of 800 ml solvent	1 ampoule containing 4,000 doses

Poulvac Solvent bag	**Number of vaccine ampoules for *in ovo* use**
Bag of 200 ml solvent	2 ampoules containing 2,000 doses
Bag of 400 ml solvent	4 ampoules containing 2,000 doses
Bag of 400 ml solvent	2 ampoules containing 4,000 doses
Bag of 800 ml solvent	4 ampoules containing 4,000 doses
Bag of 1,000 ml solvent	5 ampoules containing 4,000 doses

9. Advice on correct administration

Reconstitution should be done under aseptic conditions. Before withdrawing the ampoules from the liquid nitrogen container, protect the hands with gloves, wear long sleeves and use a face shield or goggles.

It is recommended to handle a maximum of 5 ampoules at a time. After removing the ampoule(s), the remaining ampoules should be put back immediately into the canister in the liquid nitrogen container.

Take the ampoule(s) of vaccine out of the liquid nitrogen container and thaw the vaccine by immersing in water at 25 ºC – 30 ºC, while gently swirling the ampoule(s) to disperse the content. As soon as vaccine in the ampoule is completely thawed, remove from the water, dry the ampoule and break the ampoules at its neck.

Once opened, slowly withdraw the total contents of the ampoule carefully into a 10 ml sterile disposable syringe with an 18-gauge needle. Slowly draw about 8 ml of Poulvac Solvent into the syringe. Turn the syringe 5-10 times to mix the contents well. Slowly transfer a small volume of the mixture into the empty vaccine ampoule in order to rinse the ampoule and withdraw this small amount back into the syringe.

Carefully transfer the entire content of the syringe into the Poulvac Solvent container. Remove the syringe and invert the solvent bag about 10 times to mix the vaccine. The vaccine is now ready for use.

The ready to use vaccine is a red, slightly opalescent liquid.

In case automated equipment is used for *in ovo* or subcutaneous administration, the equipment should be calibrated to ensure that the correct dose is applied to each egg or chicken. The instructions for use of this device should be followed.

The bag of vaccine should be gently swirled frequently during vaccination to guarantee that the vaccine suspension remains homogenous and that the correct vaccine virus titre is administered.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Concentrate:
Store and transport frozen in liquid nitrogen (or vapour phase) at or below -150 °C.

Poulvac Solvent:
Store at or below 25 °C. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label (solvent) or ampoule (concentrate) after Exp. The expiry date refers to the last day of that month.

Shelf life after dilution according to directions: 2 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.

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/2/23/300/001-002

Concentrate:
Type I glass ampoule containing 2,000 or 4,000 doses of the vaccine. The ampoules are stored in cryopreservation containers in a cane. The dose presentation is presented on the extremity of each cane.

Poulvac Solvent:
Polyvinylchloride (PVC) and polypropylene plastic bag containing 200 ml, 400 ml, 800 ml, and 1,000 ml.
The solvent is packed separately from the ampoules.

Not all pack sizes may be marketed.

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 and contact details to report suspected adverse reactions:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
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United Kingdom (Northern Ireland)
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

The vaccine contains a cell-associated live recombinant turkey herpesvirus (HVT) expressing the VP2 protein of infectious bursal disease virus. The vaccine induces active immunity against infectious bursal disease (Gumboro disease) and Marek's disease in chickens.