[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR effervescent tablet for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose of vaccine contains:

Active substance:
Avian infectious bronchitis virus, strain 233A var-1, live, not less than $10^{3,2}$ EID_{50} and not more than $10^{5,1}$ EID_{50}*

*EID_{50} = 50% Embryo Infectious Dose. (The statistically determined quantity of virus that may be expected to infect 50 per cent of the fertilised eggs into which it is inoculated).

Excipients:

Qualitative composition of excipients and other constituents
Trehalose
Sodium hydrogen carbonate
Citric acid
Magnesium stearate

Round, off-white effervescent tablet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broilers, layers and breeders).

3.2 Indications for use for each target species

Active immunization of broiler chickens, breeders and layers to reduce mortality, clinical signs and lesions of virulent Infectious Bronchitis.
The vaccine is recommended for use at all ages starting from day one. Single vaccination causes quick increase of immunity against infectious bronchitis virus. Breeders and layers should be also revaccinated later on, accordingly to settled vaccination programme.

Onset of immunity: 21 day after vaccination.
Duration of immunity: 42 days after vaccination. Repeated vaccination (on 1 and 14 day of age) protects fully in broiler flocks, which are slaughtered at about 7 - 8 weeks of age.

3.3 Contraindications

Do not use in unhealthy or stressed birds.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Immuno-competence of the animal may be compromised by a variety of factors including immunosuppressive diseases, nutritional status and stress.
The vaccine strain can spread to susceptible species. Special precautions should be taken to avoid spreading of the vaccine strain in multi-age sites.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, goggles and mask should be worn when handling the veterinary medicinal product.
In the case of accidental ingestion, spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

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

3.6 Adverse events

None.

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:
The vaccine can be used in layers from 1 day of age.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with live vaccines against Newcastle disease. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

Inhalation use. The vaccine can be administered via coarse spray or aerosol.
Recommended vaccination time: from 1 day of age.

Vaccine preparation
Dissolve the tablet vaccine in pure clean water (cold boiled) only. Do not use water with traces of disinfectants or detergents.
Press the blister to release the tablet into water. Wait 1-2 minutes until complete dissolution is achieved and then mix gently to ensure homogenous dispersion of the vaccine.
Vaccinate the animals only after the tablet is fully dissolved.
The reconstituted product is an almost clear, slightly cloudy suspension.
The vaccine should not be used if the entire tablet is not fully dissolved or not dissolved at all, nor if the tablet has an improper appearance such as change in colour or swollen tablet.

Do not use tablets from punctured sections of the blister.
Do not save any unused portion of vaccine for use on another day. Do not under-dose.

After reconstitution the vaccine should be used up within maximum 2 hours, but preferably it should be used up immediately.

Recommended reconstitution volume (ml):

Dosage	**Coarse spray***	**Aerosol ***
1000	50-300	100-150
2000	100-600	200-300
2500	125-750	250-375
5000	250-1500	500-750
10000	500-3000	1000-1500

* The exact amount of water depends on the output of the device used for coarse spray and aerosol.

Equipment:
Coarse spray: A coarse sprayer of the type used in gardens can be used to spray 1 day-old chicks immediately after hatching or in the brooder house. For older birds, use an electric powered sprayer or a knap sac sprayer delivering a more uniform spray. Droplets should not be smaller than 100 μm.

Aerosol: The electrical aerosol system should deliver small droplets: 40-100 μm. This method is used for repeated vaccination in older birds.

Advice on correct administration:
Devices used for coarse spray and aerosol systems should be cleaned by flowing boiled hot water. The efficiency of sprayer should be tested before vaccination.
The coarse spray and aerosol systems must be aimed 60-70 cm above the birds.
Before spraying, darken the house and turn off fans and heaters.
Provide birds with peace during and after vaccination.

Immunological response to the vaccine antigen will be reduced by inappropriate storage or administration.

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

The vaccine was found to be safe after inoculation of 1 day old SPF chicks by eye drop method, using an equivalent of at least 10 times the recommended dose.

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

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code:

QI01AA03

The vaccine stimulates active immunity against Infectious Bronchitis Disease. The vaccine contains a live attenuated Infectious Bronchitis virus propagated in fertile eggs from SPF flocks, then freeze-dried, tableted and packed in blisters.

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: 2 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

Tablets (1000, 2000, 2500, 5000 or 10000 doses) are packed in Aluminium – Aluminium double-layer blisters: Alum Soft Silver (PVC/PVDC) - Alum Silver (PVC).
Each blister contains 10 tablets.
PVC: PolyVinyl chloride; PVDC: PolyVinlylidene Chloride
Cardboard box contains 1 blister (10 tablets).

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

Phibro Animal Health (Poland) Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR effervescent tablet for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

IBV, 233A strain, $10^{3.2}$ - $10^{5,1}$ EID_{50}/dose

3. PACKAGE SIZE

10 x 1000 (2000, 2500, 5000 or 10 000) d

4. TARGET SPECIES

Chickens (broilers, layers and breeders). 

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Inhalation use (coarse spray or aerosol administration).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
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

Phibro
ANIMAL HEALTH CORPORATION ™

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

IBV, 233A strain, $10^{3,2}$ - $10^{5,1}$ EID_{50}/dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Additional information:

1000 (2000, 2500, 5000 or 10 000) d

Phibro ANIMAL HEALTH CORPORATION ™

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

TAbic IB VAR effervescent tablet for suspension for chickens

2. Composition

1 dose of vaccine contains:
Active substance:
Avian infectious bronchitis virus, strain 233A var-1, live, not less than $10^{3.2}$ EID_{50} and not more than $10^{5.1}$ EID_{50}*

*EID_{50} = 50% Embryo Infectious Dose. (The statistically determined quantity of virus that may be expected to infect 50 per cent of the fertilised eggs into which it is inoculated).

Round, off-white effervescent tablet.

3. Target species

Chickens (broilers, layers and breeders).

4. Indications for use

Active immunization of broiler chickens, breeders and layers to reduce mortality, clinical signs and lesions of virulent Infectious Bronchitis.
The vaccine is recommended for use at all ages starting from day one. Single vaccination causes quick increase of immunity against infectious bronchitis virus. Breeders and layers should be also revaccinated later on, accordingly to settled vaccination programme.

Onset of immunity: 21 day after vaccination.
Duration of immunity: 42 days after vaccination. Repeated vaccination (on 1 and 14 day of age) protects fully in broiler flocks, which are slaughtered at about 7 - 8 weeks of age.

5. Contraindications

Do not use in unhealthy or stressed birds.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Immuno-competence of the animal may be compromised by a variety of factors including immunosuppressive diseases, nutritional status and stress.
The vaccine strain can spread to susceptible species. Special precautions should be taken to avoid spreading of the vaccine strain in multi-age sites.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of gloves, goggles and mask should be worn when handling the veterinary medicinal product.
In the case of accidental ingestion, spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

Laying birds:
The vaccine can be used in layers from 1 day of age.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with live vaccines against Newcastle disease. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:
The vaccine was found to be safe after inoculation of 1 day old SPF chicks by eye drop method, using an equivalent of at least 10 times the recommended dose.

Special restrictions for use and special conditions for use:

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

7. Adverse events

None.

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: {national system details}

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

Inhalation use. The vaccine can be administered via coarse spray or aerosol.
Recommended vaccination time: from 1 day of age.

Vaccine preparation
Dissolve the tablet vaccine in pure clean water (cold boiled) only. Do not use water with traces of disinfectants or detergents.
Press the blister to release the tablet into water. Wait 1-2 minutes until complete dissolution is achieved and then mix gently to ensure homogenous dispersion of the vaccine.
Vaccinate the animals only after the tablet is fully dissolved.
The reconstituted product is an almost clear, slightly cloudy suspension.

Do not use tablets from punctured sections of the blister.
Do not save any unused portion of vaccine for use on another day. Do not under-dose.
After reconstitution the vaccine should be used up within maximum 2 hours, but preferably it should be used up immediately.

Recommended reconstitution volume (ml):

Dosage	**Coarse spray***	**Aerosol ***
1000	50-300	100-150
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10000	500-3000	1000-1500

* The exact amount of water depends on the output of the device used for coarse spray and aerosol.

Equipment:
Coarse spray (inhalation): A coarse sprayer of the type used in gardens can be used to spray 1 day-old chicks immediately after hatching or in the brooder house. For older birds, use an electric powered sprayer or a knap sac sprayer delivering a more uniform spray. Droplets should not be smaller than 100 µm.

Aerosol: The electrical aerosol system should deliver small droplets: 40-100 µm. This method is used for repeated vaccination in older birds.

9. Advice on correct administration

Devices used for coarse spray and aerosol systems should be cleaned by flowing boiled hot water. The efficiency of sprayer should be tested before vaccination.
The coarse spray and aerosol systems must be aimed 60-70 cm above the birds.
Before spraying, darken the house and turn off fans and heaters.
Provide birds with peace during and after vaccination.

Immunological response to the vaccine antigen will be reduced by inappropriate storage or administration.

Do not use this vaccine if you notice that the entire tablet is not fully dissolved or not dissolved at all, nor if the tablet has an improper appearance such as change in colour or swollen tablet.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the reach and sight of children.

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

Shelf-life after reconstitution 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

Packing size:
Tablets with 1000, 2000, 2500, 5000 or 10000 doses of vaccine packed in blisters.
Cardboard box contains 1 blister (10 tablets).

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:

Phibro Animal Health (Poland) Sp. z o.o.
ul. Towarowa 28, 00-839 Warsaw, Poland
Email: pv.polska@pahc.com
Tel: +48 607 380 360

Manufacturer responsible for batch release:

Synoptis Industrial Sp. z o.o.
ul. Rabowicka 15
62-020 Swarzędz
Poland

17. Other information

The vaccine stimulates active immunity against Infectious Bronchitis Disease. The vaccine contains a live attenuated Infectious Bronchitis virus propagated in fertile eggs from SPF flocks, then freeze-dried, tableted and packed in blisters.