

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR206, effervescent tablets for suspension for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose of vaccine contains:

Active substance

Live attenuated Avian Infectious Bronchitis Virus, strain 2-06 not less than $10^{3.2}$ and not more than $10^{4.4}$ EID₅₀*

*EID₅₀ = 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:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets for suspension.

Round off-white tablets.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broilers and future layers)

4.2 Indications for use, specifying the target species

Active immunization of chickens to reduce mortality, clinical signs and lesions associated with infection caused by variant 2 strains of IB virus.

Onset of immunity: 3 weeks post administration of a single dose at 1 day of age.

Duration of immunity: to at least 35/36 days of age.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

TAbic IBVAR206 vaccination protects chickens against respiratory signs caused by IBV variant 2 and should not replace the vaccination schedule against classical Infectious bronchitis.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinated chickens may excrete the vaccine strain following vaccination.

The vaccine strain can spread to chickens. Care should be taken to separate vaccinated from non-

vaccinated chickens. All chickens in a single poultry house should be vaccinated at the same time. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

This vaccine should only be used after it has been established that variant 2 IBV is epidemiologically relevant. Care should be taken to avoid introduction of the TABic IBVAR206 vaccine into areas where variant 2 IBV is not already present.

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 underdose. Overdosing is safer than administration of too small dose.

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

Personal protective equipment consisting of waterproof gloves, mask and safety goggles should be worn when handling the veterinary medicinal product.
After handling the vaccine, operators should wash their hands.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered simultaneously with Newcastle Disease vaccines.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product (except the situation mentioned above). Therefore the 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

The vaccine is to be administered via coarse spray (inhalation) from 1 day of age.
It is recommended to revaccinate at 10-14 days of age.
For layers, additional vaccinations may follow.
Vaccination programme should always be consulted with your veterinarian.

Coarse spray (inhalation) – this method may be used at the hatchery on 1 day old chicks right after hatching or older chicks in the chicken house.

Typical volumes that may be used for reconstitution are shown below. In some cases, these may need to be adjusted to align with the sprayer manufacturer’s instructions.

Presentation (doses per tablet)	Volume of water (ml) to be used for reconstitution - for administration in hatchery	Volume of water (ml) to be used for reconstitution - for administration in poultry house
500	125 - 150	100 - 200
1,000	250 - 300	200 - 400

1,500	375-450	300 - 600
2,000	500 - 600	400 - 800
2,500	625 - 750	500 - 1000
3,000	750 - 900	600 - 1200
3,500	875 - 1050	700 - 1400
4,000	1000 - 1200	800 - 1600
4,500	1125 - 1350	900 - 1800
5,000	1250 - 1500	1000 - 2000
10,000	2500 - 3000	2000 - 4000

Vaccination in hatchery using coarse spray (inhalation)

The vaccination at the hatchery is usually performed with an automatic sprayer which is activated as chick boxes go on the belt. Another way to apply the spray is with a hand sprayer operated manually. In both cases the droplets should be gauged to be of approximately of 100 – 200 µm (micrometres) in diameter and the spray should be such that the chicks come out wet. The volume of 25-30 ml water should contain 100 doses of vaccine and be sufficient for a 100 chicks.

Checklist before vaccination at the hatchery:

1. make sure that your equipment is clean, disinfectant and detergent free and works properly,
2. make sure you have enough cold (10-15°C), formerly boiled tap water, 250-300 ml per each 1000 doses,
3. calibrate the sprayer to deliver droplets of 100-200 µm (micrometres) of diameter,
4. add blue dye to the water,
5. test the sprayer by passing an empty box to make sure that the droplets are at the correct size and that the vaccine is evenly covering the box.

Preparations:

1. place enough tablets into water container and wait until it is fully dissolved (this takes a maximum of 5 minutes),
2. add the dissolved vaccine to the sprayer tank and mix it gently.

Application:

1. monitor the nozzles work,
2. monitor water temperature (10-15°C),
3. after reconstitution with water, the vaccine remains fully active for a period of 3 hours, but preferably should be used immediately after reconstitution.

Monitoring:

Monitor vaccination conditions by checking the blue dye on the chicks feathers and by passing a hand over the chicks to make sure they are all wet. After the spray, while the chicks are wet, keep them in a closed, properly warmed room and away from chilly wind.

Vaccination on the farm using coarse spray (inhalation)

The vaccination on the farm is applied by motor or manually operated sprayers. Also in this case the droplets should be of 100-200 µm (micrometres) diameter. The volume of clean water required for vaccine dissolving depends on the machine and the orifice delivering the spray.

Checklist before vaccination at the farm:

1. make sure that your equipment is clean, disinfectant and detergent free and works properly,
2. make sure you have enough cold (10-15°C), formerly boiled tap water, 200-400 ml per each 1000 doses,
3. calibrate the sprayer to deliver droplets of 100-200 µm (micrometres) of diameter,
4. add blue dye to the water,
5. test the sprayer by spraying on clean floor,
6. in case of sprayers operated manually test the speed of walking by spraying water.

Preparations:

1. place enough tablets into water container and wait until it is fully dissolved (this takes a maximum of 5 minutes),
2. add the dissolved vaccine to the sprayer tank and mix it gently.

Application:

1. crowd the chickens to one side of the chicken house,
2. turn the ventilation off,
3. turn on all the lights,
4. the person applying the vaccine has to go slowly up and down along the crowded group of chickens, spraying the product 50-100 cm above the heads of chickens,
5. make sure that all the birds are covered by vaccine solution,
6. turn the ventilation on 10-20 minutes after vaccination,
7. after reconstitution with water, the vaccine remains fully active for a period of 3 hours, but preferably should be used immediately after reconstitution.

The devices used for spraying should be cleaned with boiled, hot water.

The capacity of spraying device should be checked before vaccination.

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

The studies confirmed the safety of the product even at 10-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, Domestic fowl, Live viral vaccines.

ATCvet code: QI01AD07 (Avian infectious bronchitis virus)

The vaccine stimulates active immunity against Infectious Bronchitis Disease virus. The vaccine strain is classified as IB Variant 2-06 vaccine strain.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trehalose dihydrate

Sodium hydrogen carbonate

Citric acid anhydrous

Magnesium stearate

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product (except the one mentioned in section 4.8).

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 18 months.

Shelf life after dissolution or reconstitution according to directions: 3 hours.

6.4. Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Tablets (500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or 10 000 doses) are packed in Aluminium – Aluminium blisters: Alum Soft Silver (PVC/PVDC) – Alum Silver (PVC).
Each blister contains 10 tablets. Cardboard box contains 1 or 2 blisters.

Not all pack sizes may be marketed.

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

PHIBRO ANIMAL HEALTH (Poland) Sp. z o.o.
ul. Towarowa 28
00-839 Warszawa, Poland

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR206, effervescent tablets for suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

1 dose of vaccine contains:

Live attenuated Avian Infectious Bronchitis Virus, strain 2-06 not less than $10^{3.2}$ and not more than $10^{4.4}$ EID₅₀*

3. PHARMACEUTICAL FORM

Effervescent tablets for suspension.

4. PACKAGE SIZE

10 tablets of 500 (1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or 10 000) doses.

20 tablets of 500 (1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or 10 000) doses.

5. TARGET SPECIES

Chickens (broilers and future layers).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Coarse spray (inhalation).

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Dissolved product should be used within 3 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).
Protect from light.
Do not freeze.

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.
On veterinary prescription only.
To be administered under veterinary surgeon supervision only.

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

PHIBRO ANIMAL HEALTH (Poland) Sp. z o.o.
ul. Towarowa 28
00-839 Warszawa, Poland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR206, effervescent tablets for suspension for chickens.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

PHIBRO ANIMAL HEALTH (Poland) Sp. z o.o.

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

500 (1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000, 10 000) doses

4. BATCH NUMBER

Batch {number}

5. EXPIRY DATE

EXP {month/year}:

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

TAbic IB VAR206, effervescent tablets for suspension for chickens.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

PHIBRO ANIMAL HEALTH (Poland) Sp. z o.o.
ul. Towarowa 28
00-839 Warszawa, Poland

Importer responsible for batch release:

Synoptis Industrial Sp. z o.o.
Ul. Rabowicka 15
Swarzedz
Wielkopolskie
62-020
Poland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TAbic IB VAR206, effervescent tablets for suspension for chickens.

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

1 dose of vaccine contains:

Live attenuated Avian Infectious Bronchitis Virus, strain 2-06 not less than $10^{3.2}$ and not more than $10^{4.4}$ EID₅₀*

*EID₅₀ = 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 tablets.

4. INDICATION(S)

Active immunization of chickens to reduce mortality, clinical signs and lesions associated with infection caused by variant 2 strains of IB virus.

Onset of immunity: 3 weeks post administration of a single dose at 1 day of age.

Duration of immunity: to at least 35/36 days of age.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

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 (broilers and future layers)

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

The vaccine is to be administered via coarse spray (inhalation) from 1 day of age.

It is recommended to revaccinate at 10-14 days of age.

For layers, additional vaccinations may follow.

Vaccination programme should always be consulted with your veterinarian.

Coarse spray (inhalation) – this method may be used at the hatchery on 1 day old chicks right after hatching or older chicks in the chicken house.

Typical volumes that may be used for reconstitution are shown below. In some cases, these may need to be adjusted to align with the sprayer manufacturer's instructions.

Presentation (doses per tablet)	Volume of water (ml) to be used for reconstitution - for administration in hatchery	Volume of water (ml) to be used for reconstitution - for administration in poultry house
500	125 - 150	100 - 200
1,000	250 - 300	200 - 400
1,500	375-450	300 - 600
2,000	500 - 600	400 - 800
2,500	625 - 750	500 - 1000
3,000	750 - 900	600 - 1200
3,500	875 - 1050	700 - 1400
4,000	1000 - 1200	800 - 1600
4,500	1125 - 1350	900 - 1800
5,000	1250 - 1500	1000 - 2000
10,000	2500 - 3000	2000 - 4000

Vaccination in hatchery using coarse spray (inhalation)

The vaccination at the hatchery is usually performed with an automatic sprayer which is activated as chick boxes go on the belt. Another way to apply the spray is with a hand sprayer operated manually. In both cases the droplets should be gauged to be of approximately of 100 – 200 μm (micrometres) in diameter and the spray should be such that the chicks come out wet. The volume of 25-30 ml water should contain 100 doses of vaccine and be sufficient for a 100 chicks.

Checklist before vaccination at the hatchery:

1. make sure that your equipment is clean, disinfectant and detergent free and works properly,
2. make sure you have enough cold (10-15°C), formerly boiled tap water, 250-300 ml per each 1000 doses,
3. calibrate the sprayer to deliver droplets of 100-200 μm (micrometres) of diameter,
4. add blue dye to the water,
5. test the sprayer by passing an empty box to make sure that the droplets are at the correct size and that the vaccine is evenly covering the box.

Preparations:

1. place enough tablets into water container and wait until it is fully dissolved (this takes a maximum of 5 minutes),
2. add the dissolved vaccine to the sprayer tank and mix it gently.

Application:

1. monitor the nozzles work,
2. monitor water temperature (10-15°C),
3. after reconstitution with water, the vaccine remains fully active for a period of 3 hours, but preferably should be used immediately after reconstitution.

Monitoring:

Monitor vaccination conditions by checking the blue dye on the chicks feathers and by passing a hand over the chicks to make sure they are all wet. After the spray, while the chicks are wet, keep them in a closed, properly warmed room and away from chilly wind.

Vaccination on the farm using coarse spray (inhalation)

The vaccination on the farm is applied by motor or manually operated sprayers. Also in this case the droplets should be of 100-200 µm (micrometres) diameter. The volume of clean water required for vaccine dissolving depends on the machine and the orifice delivering the spray.

Checklist before vaccination at the farm:

1. make sure that your equipment is clean, disinfectant and detergent free and works properly,
2. make sure you have enough cold (10-15°C), formerly boiled tap water, 200-400 ml per each 1000 doses,
3. calibrate the sprayer to deliver droplets of 100-200 µm (micrometres) of diameter,
4. add blue dye to the water,
5. test the sprayer by spraying on clean floor,
6. in case of sprayers operated manually test the speed of walking by spraying water.

Preparations:

1. place enough tablets into water container and wait until it is fully dissolved (this takes a maximum of 5 minutes),
2. add the dissolved vaccine to the sprayer tank and mix it gently.

Application:

1. crowd the chickens to one side of the chicken house,
2. turn the ventilation off,
3. turn on all the lights,
4. the person applying the vaccine has to go slowly up and down along the crowded group of chickens, spraying the product 50-100 cm above the heads of chickens,
5. make sure that all the birds are covered by vaccine solution,
6. turn the ventilation on 10-20 minutes after vaccination,
7. after reconstitution with water, the vaccine remains fully active for a period of 3 hours, but preferably should be used immediately after reconstitution.

9. ADVICE ON CORRECT ADMINISTRATION

The devices used for spraying should be cleaned with boiled, hot water.
The capacity of spraying device should be checked before vaccination.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Do not freeze.
Shelf-life after reconstitution according to directions: 3 hours.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

TAbic IBVAR206 vaccination protects chickens against respiratory signs caused by IBV variant 2 and should not replace the vaccination schedule against classical Infectious bronchitis.

Special precautions for use in animals:

Vaccinated chickens may excrete the vaccine strain following vaccination.
The vaccine strain can spread to chickens. Care should be taken to separate vaccinated from non-vaccinated chickens. All chickens in a single poultry house should be vaccinated at the same time.

Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

This vaccine should only be used after it has been established that variant 2 IBV is epidemiologically relevant. Care should be taken to avoid introduction of the TAbic IBVAR206 vaccine into areas where variant 2 IBV is not already present.

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 underdose. Overdosing is safer than administration of too small dose.

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

Personal protective equipment consisting of waterproof gloves, mask and safety goggles should be worn when handling the veterinary medicinal product. After handling the vaccine, operators should wash their hands.

Lay:

Do not use in birds in lay or within 4 weeks before the onset of the laying period.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be administered simultaneously with Newcastle Disease vaccines.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product (except the situation mentioned above). Therefore the 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):

The studies confirmed the safety of the product even at 10-fold overdose.

Incompatibilities:

Do not mix with any other veterinary medicinal product (except the one mentioned in section Interactions).

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 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

DD/MM/YYYY

15. OTHER INFORMATION

Packing size:

Cardboard box contains 1 or 2 blisters (10 tablets of 500, 1000, 1500, 2000, 2500, 3000, 3500, 4000, 4500, 5000 or 10 000 doses).

Not all pack sizes may be marketed.

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