

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

**Tabic IB VAR** effervescent tablets for suspension for chickens.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 dose of vaccine contains:

Attenuated virus of infectious bronchitis (IBV), 233A strain – not less than  $10^{3.2}$  EID<sub>50</sub> and not more than  $10^{5.1}$  EID<sub>50</sub>.

For a full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Effervescent tablets for suspension.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Chickens (broilers, layers and breeders).

### **4.2 Indications for use, specifying the target species**

For 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. Full immunity is achieved 21 after vaccination and lasts for at least 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. Breeders and layers should be also revaccinated later on, accordingly to settled vaccination program.

### **4.3 Contraindications**

Do not use in unhealthy or stressed birds.

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.

Do not dissolve in water with traces of disinfectants or detergents.

### **4.4 Special warnings for each target species**

Dissolve the tablet vaccine in pure clean water only.

Vaccinate the animals only after the tablet is fully dissolved.

Use the vaccine solution within 2 hours of preparation.

Only healthy birds should be vaccinated.

Immuno-competence of the animal may be compromised by a variety of factors including immunosuppressive diseases, nutritional status, and stress.

The vaccine virus spreads; care should be taken to prevent such spread in multi-age sites.

#### 4.5 Special precautions for use incl. special precautions to be taken by the person administering the veterinary medicinal product to animals

Operator should wear gloves, goggles and mask in order to avoid contact with product. In the case of accidental self-injection / ingestion / spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician. Immunological response to the vaccine antigen will be reduced by inappropriate storage or administration.

#### 4.6 Adverse reactions (frequency and seriousness)

No adverse effects were seen in vaccinated birds in safety (at least x10 times the recommended dose) / efficacy studies with the vaccine.

#### 4.7 Use during pregnancy, lactation or lay

The TABic IB VAR live vaccine can be used in layers vaccinated from 1 day of age.

#### 4.8 Interaction with other medicinal products and other forms of interaction

Compatibility has been shown between TABic IB VAR and NDV vaccine when vaccinated at the same age (1 day old).

#### 4.9 Amounts to be administered and administration route

This vaccine can be administered via coarse spray or aerosol. Recommended vaccination time: starting from the 1 day of age. Press the blister to release the tablet into cold boiled water. Wait 1-2 minutes after complete dissolution achieved and then mix gently to ensure homogenous dispersion of the vaccine.

Vaccine was found to be satisfactory for a period of maximum 2 hours, but preferably the vaccine should be used immediately after reconstitution.

RECONSTITUTION VOLUME RECOMMENDATIONS (ml):

Dosage	Coarse spray*	Aerosol *
100		
500		
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.

**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 $\mu$ .

**Aerosol:** The electrical aerosol system should deliver small droplets: 40-100 $\mu$ . 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.

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

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 doses.

### **4.11 Withdrawal period(s)**

0 days.

## **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: immunological products for birds.

ATCvet code: QI01AA03

TAbic IB VAR (233A strain) is live vaccine that 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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Trehalose

Sodium Hydrogen Carbonate

Citric Acid Anhydrous

Magnesium Stearate

### **6.2 Incompatibilities**

In the absence of compatibility studies this vaccine should not be mixed with other veterinary medicinal products.

### **6.3 Shelf life**

2 years for veterinary medicinal product as packed for sale.

Shelf-life after reconstitution – maximum 2 hours.

### **6.4 Special precautions for storage**

Keep refrigerated between +2°C and +8°C. Protect from light.

### **6.5 Nature and composition of immediate packaging**

Tablets (a 1000, 2000, 2500, 5000 or 10 00 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: PolyVinylidene Chloride

Cardboard box contains 1 blister (10 tablets).

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

**7. MARKETING AUTHORISATION HOLDER**

Phibro Animal Health (Poland) Sp.z.o.o.  
Ul. Towarowa 28  
Warsaw  
00-839, Poland

**8. MARKETING AUTHORISATION NUMBER**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**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 tablets for suspension for chickens.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

IBV, 233A strain – not less than  $10^{3.2}$  EID<sub>50</sub>/dose and not more than  $10^{5.1}$  EID<sub>50</sub>.

**3. PHARMACEUTICAL FORM**

Effervescent tablets for suspension.

**4. PACKAGE SIZE**

10 tablets a 1000 (2000, 2500, 5000 or 10 000) doses.

**5. TARGET SPECIES**

Chickens (broilers, layers and breeders).

**6. INDICATION(S)**

For active immunization of broiler chickens, breeders and layers to reduce mortality, clinical signs and lesions of virulent Infectious Bronchitis.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Coarse spray or aerosol administration.

**8. WITHDRAWAL PERIOD**

0 days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

Expiry date {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store under refrigeration (2 °C - 8 °C). Protected from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

**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 REACH AND SIGHT OF CHILDREN”**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

Ul. Towarowa 28

Warsaw

00-839, Poland

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Batch number:

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Aluminium blister**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

TAbic IB VAR effervescent tablets for suspension for chickens.

**2. NAME OF THE MARKETING AUTHORISATION HOLDER**

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

**3. PACKAGE SIZE**

1000 (2000, 2500, 5000, 10 000) doses

**4. EXPIRY DATE**

Expiry date: {month/year}

**5. BATCH NUMBER**

Batch number:

**6. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### Tabic IB VAR 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 and manufacturer:

Phibro Animal Health (Poland) Sp.z.o.o.  
Ul. Towarowa 28  
Warsaw  
00-839, 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 VAR effervescent tablets for suspension for chickens.

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

1 dose of vaccine contains:

Attenuated virus of infectious bronchitis (IBV), 233A strain – not less than  $10^{3.2}$  EID<sub>50</sub> and not more than  $10^{5.1}$  EID<sub>50</sub>.

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#### 5. CONTRAINDICATIONS

Do not use in unhealthy or stressed birds.

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.

Do not dissolve in water with traces of disinfectants or detergents.

#### 6. ADVERSE REACTIONS

No adverse effects were seen in vaccinated birds in safety (at least x10 times the recommended dose) /

efficacy studies with the vaccine.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Chickens (broilers, layers and breeders).

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

This vaccine can be administered via coarse spray or aerosol.

Recommended vaccination time: starting from the 1 day of age

Press the blister to release the tablet into cold boiled water. Wait 1-2 minutes after complete dissolution achieved and then mix gently to ensure homogenous dispersion of the vaccine.

Vaccine was found to be satisfactory for a period of maximum 2 hours, but preferably the vaccine should be used immediately after reconstitution.

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## 9. ADVICE ON CORRECT ADMINISTRATION

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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.

## 10. WITHDRAWAL PERIOD

0 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.

Shelf-life after reconstitution – maximum 2 hours.  
Do not use after the expiry date stated on the blister.

## **12. SPECIAL WARNING(S)**

Dissolve the tablet vaccine in pure clean water only.

Vaccinate the animals only after the tablet is fully dissolved. Use the vaccine solution within 2 hours of preparation. Only healthy birds should be vaccinated.

Immuno-competence of the animal may be compromised by a variety of factors including immunosuppressive diseases, nutritional status, and stress.

The vaccine virus spreads; care should be taken to prevent such spread in multi-age sites.

Operator should wear gloves, goggles and mask in order to avoid contact with product.

In the case of accidental self-injection / ingestion / spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

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

The TABic IB Var live vaccine can be used in layers vaccinated from 1 day of age.

Compatibility has been shown between TABic IB Var and NDV vaccine when vaccinated at the same age (1 day old).

In the absence of compatibility studies this vaccine should not be mixed with other veterinary medicinal products.

## **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**

## **15. OTHER INFORMATION**

For any information about this veterinary medicinal product, please contact marketing authorisation holder.

Packing size:

Cardboard box contains 1 blister (10 tablets at 1000, 2000, 2500, 5000, 10 000 doses).