



FATRO  
industria farmaceutica veterinaria

# **ENCEFAL-VAC**

## SUMMARY OF PRODUCT CHARACTERISTICS

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### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

#### **ENCEFAL-VAC**

Live lyophilised vaccine for chickens

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### **Active substance:**

Live attenuated virus of avian encephalomyelitis, CALNEK 1143 strain.

Titre: not less than  $10^3$  EID<sub>50</sub>/dose

For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Lyophilisate for oral suspension

### 4. CLINICAL PARTICULARS

4.1 Target species: chicken (layers and breeders)

4.2. Indications for use, specifying the target species  
ENCEFAL-VAC is indicated for oral immunological prophylaxis (through the drinking water) against avian encephalomyelitis in chickens. It prevents mortality, clinical symptoms and lesions of the disease. Protection starts 3-4 weeks after vaccination and lasts for the entire reproductive life of the hens.

4.3 Contraindications: none.  
See also section 4.7.

4.4 Special warnings for each target species  
Do not use during egg production and in the 4 weeks prior to this.  
Do not vaccinate chickens of an age of less than 2 months  
To ensure good results from the vaccination, it is better to adhere to the following regulations:  
- ensure that the drinkers and drinking water do not contain antiseptic substances or disinfectants which, even in traces, could inactivate the vaccine virus;



- use, where possible, plastic, glass or enamel drinkers;
- thirst the birds, suspending administration of drinking water for at least three hours prior to vaccination;
- distribute the vaccine suspension obtained from reconstitution of the preparation, to a number of drinkers, so as to allow all the birds to consume the vaccine in the space of two-three hours after its preparation;
- do not expose water containing the vaccine to sources of heat.

Administered only to animals in good health

#### 4.5 Special precautions for use

##### *Special precautions for use in animals*

Appropriate veterinary and husbandry measures must be adopted to avoid spread to sensitive species

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

The operator must wash his hands carefully, avoiding any contact of the vaccine with the eyes. People with known hypersensitivity towards the product must avoid contact.

#### 4.6 Adverse reactions (frequency and severity):

None known

#### 4.7 Use during pregnancy, lactation or egg production

Do not use in birds during egg production and in the 4 weeks prior to this

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

No information is available on the safety and efficacy of concurrent use of this vaccine with any other. Therefore safety and efficacy have not been demonstrated when used with other vaccines.

#### 4.9 Posology and administration route

ENCEFAL-VAC is efficacious when administered orally via the drinking water.

To obtain the vaccine suspension, a small quantity of water must be added to the contents of the bottle and dissolved carefully. At this point, the suspension is poured into the quantity of drinking water considered necessary for vaccination, rinsing the bottle to avoid residues of vaccine powder remaining unused.



When the entire contents of the bottle have been dissolved in the drinking water, care should be taken to immediately mix well before administration to the birds, which must take place in the shortest time possible.

The quantity of water required for vaccination varies according to the age of the birds, the season and the ambient temperature. The minimum and maximum quantities of water recommended with regard to the first of the above-mentioned variables are shown below:

Age of chickens (weeks)	Quantity of water (litres) 1000 doses
8-12	20-60
over 12	50-80

#### Vaccination programme

ENCEFAL-VAC is used for the vaccination of future layers and breeders, in order to avoid any mortality due to Encephalomyelitis in chicks and a decrease in egg production.

The most suitable age for vaccination is between the third and the fourth month.

It is recommended that an interval of at least 14 days between other vaccinations should be maintained. Chickens of an age less than 2 months or in egg production must not be vaccinated, therefore vaccination must be performed at least 1 month before going into lay.

- 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary  
Administration of a dose even 10 times higher than that recommended does not cause particular reactions.
- 4.11 Withdrawal periods  
Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

For active immunity against Avian encephalomyelitis in pullets. It induces passive immunity in chicks born to vaccinated hens.

ATC Vet code: QI01ADO2



## 6. PHARMACEUTICAL PARTICULARS

- 6.1 List of excipients  
glucose  
sodium chloride

- 6.2 Incompatibilities  
In administration, the use of water containing disinfectant substances must be avoided, as this could neutralise the vaccine virus. Do not mix this product with other vaccines.

- 6.3 Shelf-life  
Shelf-life of the veterinary medicinal product as packaged for sale: 18 months. Once diluted, the vaccine must be used immediately and assumed with 2-3 hours.

- 6.4 Special precautions for storage  
ENCEFAL-VAC, not yet reconstituted, must be stored in a refrigerator at a temperature between +2°C and +8°C.

- 6.5 Nature and composition of the immediate packaging  
The containers are made up of white Type I glass bottles closed with elastomer stoppers and aluminium collars, both having a diameter of 20 mm.  
The volume of each individual container is 10 ml; the contents are lyophilised vaccine.

- 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 appropriate authorities. Any unused product or waste materials should be disposed of in accordance with national requirements.

## 7. MARKETING AUTHORISATION HOLDER

FATRO S.p.A. - Via Emilia, 285 - Ozzano dell'Emilia - Bologna - Italy  
Production plant: Maclodio (Brescia, Italy), Via Molini Emili 2

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

1000 dose bottle	no. 101814010
Pack of 10 x 1000 dose bottles	no. 101814022

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

15.02.1979 / 31.12.2002 /

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

April 2008

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

Not applicable

**DISPENSATION REGIME**

Medicinal product subject to non-renewable veterinary medical prescription in three copies