LAR-VAC

SUMMARY OF PRODUCT CHARACTERISTICS

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LAR-VAC
Live freeze-dried vaccine for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: live attenuated virus of avian infectious laryngotracheitis.
Titre: not less than $10^{3.2}$ $TCID_{50}$/ dose;

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Freeze-dried vaccine and diluent for suspension for eye drop administration.

4. CLINICAL PARTICULARS

4.1 Target species:
chicken

4.2. Indications for use, specifying the target species
Immunological prophylaxis to prevent mortality, symptoms and lesions of infectious laryngotracheitis in the chicken.
Immunity is established 10-15 days after vaccination.

4.3 Contraindications
None known

4.4 Special warnings for each target species
None

4.5 Special precautions for use

Special precautions for use in animals
LARVAC must be used in birds older than 21 days, after ascertaining their good general state of health.
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
Wash the hands after use.
In cases of accidental ingestion, see a doctor immediately and show him the package leaflet or label of the product.

4.6 Adverse reactions (frequency and severity)
In vaccinated birds, it can cause a mild conjunctival reaction which disappears within 5-8 days.

4.7 Use during pregnancy, lactation or egg production
Do not administer during egg production.

4.8 Interaction with other medicinal products and other forms of interaction
No information is available on the compatibility of the vaccine with others. Consequently, the safety and efficacy of the product used with others has not been demonstrated.

4.9. Amounts to be administered and administration route
LARVAC is administered by eye drop administration.
The contents of the bottle of vaccine are dissolved in the diluent; then, using a suitable dropper, one drop is inoculated into an eye and one drop in a nostril.

Vaccination programme
In broilers it is recommended that one vaccination be performed at 21-28 days, followed, if necessary, by a second at 40 days with a half dose.
In layers, in addition to vaccination at the age of 4-6 weeks, a second vaccination is necessary before going into lay, that is to say between the 15th and the 20th week.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
The administration of a dose even 10 times higher does not aggravate the conjunctival reactions which may occur.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against avian infectious laryngotracheitis
ATC Vet code: QI01AD08

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose
Peptone
Sodium chloride
Patent Blue
Purified water

6.2 Incompatibilities
Not applicable

6.3. Shelf-life
Shelf-life of the medicinal product as packaged for sale: 18 months
Once diluted, the vaccine must be used within one-two hours.

6.4 Special precautions for storage
LARVAC, 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
Containers for the vaccine: these are made up of white Type III glass bottles closed with elastomer stoppers and aluminium collars, both having a diameter of 20 mm. The capacity of each individual container is 5 ml; their contents are freeze-dried vaccine.
Containers for the diluent: polyethylene bottle with dropper

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 materials 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
Manufacturing plant: Via Molini Emili 2 - Maclodio - Brescia - Italy

8. MARKETING AUTHORISATION NUMBER(S)

1000 dose bottle no. 101815013

9. DATE OF FIRST AUTHORISATION /RENEWAL OF AUTHORISATION

28.05.1988 /

10. DATE OF REVISION OF THE TEXT

20.09.2008

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

DISPENSING

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