

HIPRAVIAR S

Lyophilisate for suspension

QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVES SUBSTANCES:

One dose (0.03 ml) contains:

Attenuated live Newcastle Disease virus, strain La Sota: $10^{6.5} - 10^{8.5}$ EID₅₀*

*50% infective dose in chicken embryos.

INDICATIONS FOR USE:

For the active immunization of poultry to prevent the infection by Newcastle Disease in broilers, breeders and layers.

CONTRAINDICATIONS:

Not applicable.

ADVERSE REACTIONS:

Respiratory symptoms may occur in vaccinated birds at 5-7 days post-vaccination.

If you notice any serious effects not mentioned in this leaflet, please inform your veterinarian.

TARGET SPECIES:

Poultry (broilers, breeders and layers).

POSOLOGY FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION:

Poultry: 1 dose/bird.

Ocular-nasal, drinking water or spray.

The veterinary surgeon will establish the most suitable vaccination programme according to the health conditions of each farm and area.

ADVICE ON CORRECT ADMINISTRATION:

Ocular-nasal: Mix the solvent and the lyophilized using the decanted supplied and gently shake until complete reconstitution of lyophilized prior to administration. Administer one drop of the vaccine (0.03 ml) per bird, in the eye or nare, using the supplied dropper (30 ml per 1,000 doses).

Drinking water: Dissolve the freeze-dried powder by filling the flask in which it is contained to half volume with fresh tap water (do not use chlorinated water or with disinfectants and avoid high temperatures in coater), shake and pour it into an adequate container up to a volume of drinking water that can be ingested within 1/2 or 1 hour at most, keeping in mind that:

Age of the bird	Approx. amount of water for 1,000 birds
1 to 3 weeks	5 to 10 litres
4 to 9 weeks	12 to 23 litres
10 to 16 weeks	27 to 37 litres

Avoid high temperatures of water where the freeze-dried tableted is diluted.

To ensure that vaccine water is ingested within 1/2 or 1 hour at most, it is advisable not to administer water to animals for one hour before vaccination in the summer and for two hours in winter.

Nebulisation: Validate the apparatus to be used for checking the necessary amount of water, as it totally depends on the type of apparatus and the size of drop it produces. To do so, fill that apparatus with fresh tap water the day before vaccination and spray it on the birds in such a way that all of their heads are covered with drops of water. Check the quantity of water used and this will be the amount that will have to be used to mix with the necessary doses, depending on the number of birds to be vaccinated. The following volumes are approximate:

No. of doses	1-day-old chicks (large drops)	Older birds (fine drops)
1,000	200-250 ml	500-1,000 ml

WITHDRAWAL PERIOD:

Zero days.

SPECIAL PRECAUTIONS FOR STORAGE:

Keep out of the sight and reach of children.

Store and transport refrigerated (+2 to +8 °C).

Do not freeze. Protect from light.

Once reconstituted, use immediately.

SPECIAL WARNINGS:

Special warnings for each target species

Vaccinate only healthy animals.

If the number of birds does not coincide with the number of doses of available vials, an overdose should be administered, never administered less than the recommended dosage.

Special precautions for use in animals

Check the shelf life of the product.

Do not expose the vaccine to disinfectants, detergents, heat or sunlight, as it is sensitive to them.

Avoid high temperatures in water where the freeze-dried fraction is diluted.

Birds can be vaccinated 1 day after hatching, if they are placed into an endemic area of Newcastle disease.

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

Spray administration requires the use of protective mask and glasses.

Use during lay

Do not use in lay.

Interactions with other vaccines and medicinal products when administered in combination with the product

No information is available on the safety and efficacy of this vaccine when used with any veterinary medicinal product.

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 administration of 10 times the recommended dose does not cause any alteration other than those mentioned in point "ADVERSE REACTIONS".

Incompatibilities

In absence of compatibility studies, do not mix with any other veterinary medicinal product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED 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 products should be disposed of in accordance with local requirements.

OTHER INFORMATION:

Pack sizes:

Pack of 10 vials of 100 doses.

Pack of 10 vials of 500 doses.

Pack of 10 vials of 1,000 doses.

Pack of 10 vials of 2,500 doses.

Pack of 10 vials of 5,000 doses.

Pack with 10 vials of solvent of 1,000 doses.

Not all pack sizes may be marketed.

Reg. n° 5/5/10/8579
Under veterinary prescription

FOR VETERINARY USE ONLY



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