SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HuveGuard NB suspension for oral suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.025 ml contains:

Active substances:

Sporulated oocysts from two attenuated precocious lines of *Eimeria* species:

Eimeria necatrix, strain mednec 3+8 100 –310 oocysts*
Eimeria brunetti, strain roybru 3+28 50 –155 oocysts*

* According to the in vitro counting procedure of the manufacturer at the time of blending and at release

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for oral suspension.
Colourless to white to light beige suspension when shaken.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For the active immunisation of chickens to reduce infection and clinical signs of coccidiosis caused by *E. necatrix* and *E. brunetti*.

Onset of immunity: 21 days post vaccination.
Duration of immunity: not demonstrated.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
The vaccine contains live coccidian oocysts and is dependent upon replication of the vaccine strains within the chickens for building up of immunity. It is common to find oocysts in the gastro-intestinal tract of vaccinated birds from 1–3 weeks or more after

vaccination. These oocysts are most likely to be vaccinal oocysts which recycle in the birds via the litter. Recycling of oocysts is necessary for the development of immunity and for continued protection.

Since the protection against coccidial infection following vaccination is enhanced by natural challenge, access to any therapeutic agents having anti-coccidial activity at any time following vaccination can adversely affect the development of immunity. This is important throughout the life of the chicken.

4.5 Special precautions for use

Special precautions for use in animals
Chickens must be strictly floor reared on litter.
To reduce the chance of coccidial challenge before the onset of immunity, litter should be removed and chicken housing should be thoroughly cleaned between rearing cycles.

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

Wash and disinfect hands and equipment after use.
When spraying the vaccine onto chicks or onto feed, personal protective equipment consisting of a well-fitting mask and eye protection should be worn by the operator.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer any anticoccidial agents, including sulphonamides, before or after vaccination, as doing so will have a negative impact on immunity which is dependent on the recycling of oocysts in the environment.

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

4.9 Amounts to be administered and administration route

Oral use (spray on birds, spray on feed and drinking water)

Vaccination schedule:
Spray on birds and spray on feed: administer one dose of vaccine to each chicken from 1 day of age.
Drinking water: administer one dose of vaccine to each chicken from 3 days of age.

Once the 30 ml containing 1,000 or 5,000 doses vial is opened, the entire contents must be used.

Administration via spray onto feed
Sufficient starter feed for the chicks' first 12-24 hours should be laid out on paper or plastic along the floor of the poultry house.

Shake the vaccine vial vigorously for 30 seconds before use to re-suspend the oocysts. Dilute the vaccine in water at the rate of approximately 1000 doses in 1 litre of water (5000 doses in 5 litres). To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Spray the oocyst suspension evenly over the surface of the feed using a coarse spray. Ensure a controlled even coverage of the total surface area of the feed available to the chickens. Agitate the applicator reservoir regularly throughout spraying to avoid settling-out of oocysts. Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house.

Once the vaccine has been diluted for use it should be sprayed immediately onto feed and birds should be placed with access to the feed immediately.

When the treated allocation of feed has been consumed, routine feeding may continue.

It is recommended to monitor the feed intake and behaviour of the birds and to apply the vaccine by this method only after an adequate feed intake is expected.

Administration via drinking water
For the administration of the vaccine drinkers must be used.
Provide an adequate number of drinkers and drinking space so that all chicks have access to the vaccinal water and thus can receive the correct dose.
Place the drinkers evenly in the area where chicks are housed.

Water should be withheld for 2–4 hours before vaccination.

Preparation of the xanthan gum suspension:
Commercially available xanthan gum can be used.
For 1,000 doses put 3 litres of clean drinking water at room temperature in a suitable container and dissolve 5 g xanthan gum.
For 5,000 doses put 15 litres of clean drinking water at room temperature in a suitable container and dissolve 25 g xanthan gum.

Prepare the vaccine suspension as follows:
To resuspend the oocysts, shake the vaccine vial vigorously. Open the vial and pour the whole contents into clean drinking water at room temperature: 2 litres for 1,000 doses and 10 litres for 5,000 doses. To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Shake the obtained 2 litres (1,000 doses) or 10 litres (5,000 doses) of vaccine suspension and transfer gradually into the prepared xanthan gum suspension, mixing thoroughly to ensure a homogeneous suspension. Mixing the xanthan gum together with the vaccine suspension will result in a final quantity of 5 litre (for 1,000 doses) or 25 litre (for 5,000 doses) vaccine-xanthan gum suspension. Pour the vaccine-xanthan gum suspension into the drinking equipment.

Administration via spray on chickens.
For each 100 birds a dose volume of about 24 ml (0,24 ml/bird) of coarse spray suspension has to be prepared.

For spraying on chickens use Brilliant Blue (E133) coloring agent.

Preparation of the coloured diluent:
For 1000 doses put 240 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.
For 5000 doses put 1200 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.

Preparation and administration of the vaccine suspension:
Shake the 1000- or 5000- doses vial vigorously to resuspend the oocysts.
Add the entire content of the vial to the diluent and mix thoroughly. Rinse the vial 3 times with diluent to ensure that all oocysts are removed. Fill the vaccine reservoir of the spraying device with the full volume prepared. Continuously maintain homogeneity of the vaccine suspension. The pressure of the spraying device should be at 3 bars. The spraying device must provide a droplet size of ≥100 µm.
To improve the uniformity of the vaccination maintain the chicks inside the chick box for at least 1 hour in order to let them ingest all the vaccine droplets. Make sure that there is enough light so that the chickens are awake and preen themselves and each other.

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

No side effects have been observed following administration of a 10-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live parasitic vaccines for domestic fowl.
ATCvet code: QI01AN01.

To stimulate active specific immunity to wild strains of *E. necatrix* and *E. brunetti* when ingested by chickens. Vaccination is followed by continuous and lifelong recycling of vaccinal oocysts in birds via the litter. This recycling of oocysts results in the development of immunity and continued protection against wild strains of both *Eimeria* strains.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium chloride
Disodium phosphate
Potassium dihydrogen phosphate
Polysorbate 80
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 22 weeks.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: 4 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene (LDPE) vial of 30 ml with a grey butyl rubber stopper and aluminium cap containing either 1,000 or 5,000 doses.
Pack sizes:
Cardboard box with 1 vial of 1000 doses
Cardboard box with 1 vial of 5000 doses
Cardboard box with 5 vials of 1000 doses
Cardboard box with 5 vials of 5000 doses
Cardboard box with 10 vials of 1000 doses
Cardboard box with 10 vials of 5000 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Huvepharma N.V.
Uitbreidingstraat 80
2600 Antwerp
Belgium

8. MARKETING AUTHORISATION NUMBER

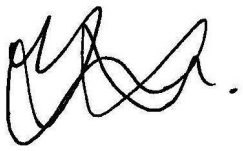
Vm 30282/4032

9. DATE OF FIRST AUTHORISATION

19 August 2016

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 21 September 2020