SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryomarex Rispens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:
Active ingredient:
Marek's disease virus, Rispens strain, attenuated at least 1000 PFU
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For active immunisation of chickens to reduce mortality, clinical signs and lesions linked to Marek's disease.

The onset of protection is from 5 days following vaccination. While the duration of immunity has not been investigated under laboratory conditions, a single vaccine dose is considered sufficient to provide protection throughout the risk period.

4.3 Contraindications

None
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4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy birds should be vaccinated.
Rispens strain virus is excreted by vaccinates and may spread to in-contact birds. Safety and reversion to virulence trials have shown that the spread to in-contact birds can be considered as safe.

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

The operator should be aware of the general precautions to be taken when handling liquid nitrogen. Due to its very low temperature, liquid nitrogen will cause severe injury if it is in contact with the body. Ampoules may explode with considerable violence on sudden temperature changes; therefore the operator should protect himself with gloves and a visor. Protective clothing should be worn that leaves no areas of the skin exposed. In the event of accidental splashing of liquid nitrogen, immediate and copious irrigation of the eye with water is very important. Special care must be taken if finger rings are worn, as these will freeze rapidly.

First aid treatment of frostbite injuries: warm affected part by immersion in water at 29°C ± 1°C or use body heat. There will be considerable pain during warming, but this is normal. Do not rub affected area; seek expert medical help as soon as possible.

When removing an ampoule from a cane, hold the palm of a gloved hand away from the body and face. After handling the vaccine, operators should wash and disinfect hands with an approved disinfectant.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks of the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

The concurrent administration of some antibiotics may make the vaccine ineffective, it is therefore recommended not to administer antibiotics at the same time as the vaccine before taking appropriate advice from your medicine prescriber.

No information is available on the safety and the efficacy from the concurrent use of this vaccine with any other except Boehringer Ingelheim's vaccine containing recombinant HVT expressing the protective antigen of the infectious bursal disease virus, Boehringer Ingelheim's H120 Infectious Bronchitis vaccine and Boehringer Ingelheim's frozen Marek's disease HVT vaccine, where these vaccines are authorised. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

4.9 Amounts to be administered and administration route

Reconstitution of the vaccine

Do not use alone: a 1,000 doses ampoule should be reconstituted with 200 ml of Boehringer Ingelheim's authorised diluent for frozen vaccines against Marek's disease and a 2,000 doses ampoule with 400 ml of Boehringer Ingelheim's authorised diluent for frozen vaccines against Marek's disease.

Remove from the liquid nitrogen container only those ampoules which are to be used immediately.

Thaw rapidly the contents of the ampoules by agitation in water at 25- 30°C.

As soon as they are completely thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

Once the ampoule is opened, draw up the contents of the vaccine into a 5-ml sterile syringe.

Transfer the suspension into a bag of diluent previously brought to ambient temperature (20°C ± 5°C).
Draw up 2 ml of the contents of the bag of diluent into the syringe.
Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the bag of solvent.
Repeat the rinsing operation once or twice.
The diluted vaccine prepared as described is mixed by slight agitation so as to be ready for use. It should be used immediately after preparation (all of the diluted vaccine should be used up within one hour). This is why the vaccine suspension should only be prepared as and when required.
Gently agitate the bag of diluted vaccine from time to time so as to mix the vaccine suspension during the vaccination process.
Use sterile and antiseptic- and/or disinfectant-free equipment for injection purposes.
Adjust the syringe and monitor the injection in process so as to maintain the dose volume at 0.2 ml.

Posology
One single injection of 0.2 ml per chick when leaving the hatchery (at the age of one day).

Method of administration
The vaccine can be administered either by intramuscular route in the thigh or breast or by subcutaneous route in the lower part of the neck. In the first instance, it is recommended to compress the thigh muscles between the thumb and index finger to cause a slight muscular eminence. The needle must be introduced in parallel to the tibiotarsus.

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

No side effect.

4.11 Withdrawal period(s)

Zero days

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Live attenuated vaccine against Marek's disease.
The vaccine stimulates active immunity of chickens against Marek's disease.
ATC vet code: QI01AD03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bovine substrate
Dimethyl sulfoxide
Protein hydrolysate
Disaccharide

Phenol red sodium salt
Salts

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other medicinal products except with Boehringer Ingelheim's authorised diluent for frozen vaccines against Marek's disease.

6.3 Shelf life

Shelf life of the non-diluted vaccine: 37 months at -196°C.
Shelf life of the diluted vaccine: 1 hour at a temperature lower than 25°C.

6.4 Special precautions for storage

Store and transport the vaccine in liquid nitrogen.

6.5 Nature and composition of immediate packaging

(glass) ampoule of 1,000 doses of vaccine, 5-ampoule carrier, 5-carrier canister, liquid nitrogen container for 1 to 6 canisters.
(glass) ampoule of 1,000 doses of vaccine, 5-ampoule carrier, 16-carrier canister, liquid nitrogen container for 1 to 6 canisters.
(glass) ampoule of 1,000 doses of vaccine, 5-ampoule carrier, 21-carrier canister, liquid nitrogen container for 10 canisters.
(glass) ampoule of 2,000 doses of vaccine, 5-ampoule carrier, 5-carrier canister, liquid nitrogen container for 1 to 6 canisters.
(glass) ampoule of 2,000 doses of vaccine, 5-ampoule carrier, 16-carrier canister, liquid nitrogen container for 1 to 6 canisters.
(glass) ampoule of 2,000 doses of vaccine, 5-ampoule carrier, 21-carrier canister, liquid nitrogen container for 10 canisters.

Not all pack sizes may be marketed.

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 in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4104

9. DATE OF FIRST AUTHORISATION

30 August 1994

10. DATE OF REVISION OF THE TEXT

27 May 2020

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