MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (1000 and 2000 dose vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryomarex RISPENS

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 doses
2000 doses

4. ROUTE(S) OF ADMINISTRATION

I.M./S.C. route

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. FURTHER INFORMATION

Read the package leaflet before use

Boehringer Ingelheim Animal Health UK Ltd

PACKAGE LEAFLET FOR:

Cryomarex Rispens suspension for injection for chickens.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

UK: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

IE: Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release:

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
99 rue de l'Aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cryomarex Rispens

Suspension for injection for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each dose of vaccine contains:

Active substance:
Attenuated Marek's disease virus, Rispens strain, at least 1000 PFU

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE CONDITIONS

Keep out of the reach and sight of children.
Store and transport the vaccine in liquid nitrogen.

Do not use after the expiry date stated on the ampoule.
Shelf life of the diluted vaccine: 1 hour at a temperature lower than 25°C.

12. SPECIAL WARNING(S)

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.

Use during pregnancy, lactation or lay

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

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

April 2020

15. OTHER INFORMATION

UK	POM-VPS	Vm 08237/4104

IE: VPA 10454/030/001 POM Prescription only medicine.

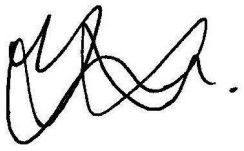
Glass ampoules of 1,000 doses and 2,000 doses of vaccine, 5-ampoule carrier, 5-carrier canister, liquid nitrogen container for 1 to 6 canisters.

Glass ampoules of 1,000 doses and 2,000 doses of vaccine, 5-ampoule carrier, 16-carrier canister, liquid nitrogen container for 1 to 6 canisters.

Glass ampoules of 1,000 doses and 2,000 doses of vaccine, 5-ampoule carrier, 21-carrier canister, liquid nitrogen container for 10 canisters.

Some pack sizes may not be marketed.

For animal treatment only.
To be supplied only on veterinary prescription.



Approved: 27 May 2020