

CRYOMAREX RISPENS + HVT

CRYOMAREX RISPENS + HVT is a frozen modified live vaccine against Marek's disease resulting from the association of the heterologous strain HVT-FC 126 (turkey herpesvirus) and of the homologous strain RISPENS (or CVI 988, belonging to serotype 1 of Marek's disease virus).

This vaccine is presented in one ampoule containing a suspension of chicken embryo live cells infected either by the HVT-FC 126 virus or by the CVI 988 virus. Immediately prior to use, the ampoule is thawed and its contents resuspended in a vial of solvent.

CRYOMAREX MAREK + HVT vaccine is used for active immunization of chickens to reduce mortality, clinical signs and lesions linked to Marek's disease.

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.

Production

The product is manufactured by Boehringer Ingelheim Lyon.

Production is carried out in GMP-accredited manufacturing facilities that are regularly inspected by the French Authorities.

The active ingredients are produced in SPF chicken embryo cells into roller bottles. An excipient (Dimethyl sulfoxide) is added during freezing, to protect cells infected by the vaccinal virus.

The vaccine is filled into glass ampoules, which are sealed, placed in holders and frozen.

Stability studies have been carried out on 3 production batches and the shelf life is 36 months for storage in liquid nitrogen.

Safety

The safety of CRYOMAREX RISPENS + HVT was demonstrated both in laboratory and in field conditions.

The safety of the vaccine was demonstrated in laboratory by inoculating an overdose (10 doses) per animal.

In the field, the safety of the product was demonstrated in a trial involving more than 1 million chicks from different breeding farms of 9 countries. They were vaccinated by intramuscular route.



**Boehringer
Ingelheim**

**PART I
CRYOMAREX RISPENS + HVT**

**No 284/E-07
February 2020**

Efficacy

The efficacy of CRYOMAREX RISPENS + HVT was demonstrated both in laboratory and in field conditions, using different routes of administration.

In the laboratory, the vaccine was found protective against virulent challenge, after inoculation of a minimum vaccine dose.

In the field, the efficacy of the product was demonstrated in a trial involving more than 1 million chicks from different breeding farms of 9 countries. They were vaccinated by intramuscular route.