MIXOHIPRA H

Lyophilisate and solvent for suspension for injection

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT:
Marketing authorisation holder and manufacturer:
Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona) Spain

STATEMENT OF THE ACTIVE SUBSTANCE(S):
Each dose (0.5 ml (subcutaneous route) and 0.1 ml (intradermal route)) contains:
Active substance:
Live attenuated myxomatosis virus (Sanarelli); strain VMI 30 $\geq 10^3$ $CCID_{50}$
$CCID_{50}$: cell culture infective dose 50%.

INDICATIONS:
For the active immunisation of rabbits against infection caused by Myxomatosis virus.
The onset of immunity is 1 week after administration and its duration is 6 months after vaccination.

CONTRAINDICATIONS:
Do not use the vaccine on immunosuppressed animals.

ADVERSE REACTIONS
Uncommon: a small nodule of 4 to 7 mm diameter may appear at the inoculation point that is reabsorbed in 2-3 weeks.
The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

TARGET SPECIES:
Rabbits (breeding rabbits and fattening rabbits).

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION:
1 dose/rabbit irrespective of age or weight.
Dosage:
Subcutaneous route 0.5 ml/rabbit.
Intradermal route 0.1 ml/rabbit by means of Dermojet system.
Vaccination programme:
Breeding rabbits:
First vaccination: vaccinate at 2.5 months old with a single dose. It is advisable to vaccinate in spring or autumn.
Re-vaccination: every 6 months.
Fattening rabbits:
First vaccination: vaccinate at 30 days old with a single dose.
Re-vaccination: Not applicable.

ADVICE ON CORRECT ADMINISTRATION:
Subcutaneous route: Dilute the lyophilisate with the attached solvent. Administer a dose of 0.5 ml per rabbit by the subcutaneous route in the back or neck.
Intradermal route: Dilute the lyophilisate with a fifth part (1/5) of the attached solvent. Administer a dose of 0.1 ml per rabbit by the intradermal route using the Dermojet system in the middle part of the outer ear.

WITHDRAWAL PERIOD:
Zero days.

SPECIAL STORAGE PRECAUTIONS:
Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC – 8 ºC).
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

SPECIAL WARNING(S):
Special warnings for each target species
- Vaccinate healthy animals only; immunosuppressive factors diminish the efficacy of the vaccine.
- Administration using Dermojet induces superior protective levels than those obtained by using the subcutaneous route, but less lasting.
- The efficacy of the vaccinations during the hot months is reduced, since the susceptibility of the rabbit to the vaccine virus diminishes.
- Immunisation with the vaccine may be interfered with by passive immunity (maternal antibodies), that disappear at 25-30 days of life. For this reason, vaccinating rabbits less than 30 days old is not advisable.
Special precautions for use in animals
- Use sterile material for its administration.
- Shake gently until complete resuspension of the lyophilisate before administration.
- Since this is a homologous vaccine with a high replication power, if the herd suffers from chronic diseases such as *Pasteurella* or *Bordetella*, these can reactivate after vaccination.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.
Use during pregnancy, lactation or lay
Can be used during pregnancy and lactation.
Interaction with other medicinal products and other forms of interaction
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.
Overdose (symptoms, emergency procedures, antidotes)
No adverse reactions other than those mentioned in section "Adverse reactions" were observed after the administration of 3 doses of vaccine.
Incompatibilities
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

OTHER INFORMATION:
Package sizes:
Cardboard box containing 1 vial with 25 doses of lyophilisate + 1 vial with 12.5 ml of solvent.
Cardboard box containing 1 vial with 40 doses of lyophilisate + 1 vial with 20 ml of solvent.

Not all pack sizes may be marketed.

Dispensation conditions: To be supplied only on veterinary prescription.
Administration conditions: Administration under control or supervision of the veterinary.

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