

PESTORIN RHDV 2, suspension for injection

1. 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 responsible for batch release:

Bioveta, a. s.
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
PESTORIN RHDV 2, suspension for injection for rabbits

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

Composition - 0.5 ml (1 dose):

Active substance:

Calicivirus septemiciae haemorrhagiae cuniculi
inactivatum, type 2 (RHDV 2) min. 80*

* Titre of haemagglutination inhibition
antibodies after application of the vaccine to
laboratory animals (rabbit)

Adjuvants: Aluminium hydroxide hydrous for
adsorption 2% 0.1 ml

Excipients: Thiomersal 0.05mg

4. INDICATION(S)

For active immunisation of rabbits without
maternally derived antibodies from the age of 4
weeks for prevention of mortality caused by the
rabbit haemorrhagic disease type 2 virus
(RHDV2).

Onset of immunity: 7 days after vaccination.

Duration of immunity: 6 months after
vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Have not been reported.

7. TARGET SPECIES

Rabbits

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

The vaccination dose is 0.5 ml, administered
subcutaneously

Animals are vaccinated at the age of 4 weeks.

Revaccination: at 6-month intervals.

Example of possible vaccination schemes:

Rabbits from non-vaccinated female rabbits
against RHDV2:

Age	4 weeks	10 weeks	Every 6 months
Vaccination	Pestorin RHDV 2 Myxoren	Pestorin Mormyx (or Pestorin + Myxoren)	Pestorin RHDV 2 Pestorin Mormyx

Rabbits from vaccinated female rabbits against
RHDV2:

Age	6 weeks	10 weeks	Every 6 months
Vaccination	Pestorin RHDV 2 Myxoren	Pestorin Mormyx (or Pestorin + Myxoren)	Pestorin RHDV 2 Pestorin Mormyx

For rabbits born to vaccinated female rabbits against RHDV2 or in the case that immune
status of the rabbit mothers is unknown the vaccination schema should be adjusted based of
consideration of an veterinary surgeon to interference of maternally derived antibodies of the
response on the vaccination will be taken into account. In case of a high infectious pressure
with myxomatosis, it is recommended to vaccinate against myxomatosis from 4 weeks of
age.

9. ADVICE ON CORRECT ADMINISTRATION

Prior to application shake.

Do not use Pestorin RHDV 2 suspension for
injection for rabbits if you notice a visible signs
of deterioration of primary packaging material.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C–8 °C).
Protect from frost.

Protect from light.

Do not use this veterinary medicinal product
after the expiry date which is stated on the
label.

Shelf life after first opening the container:

10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species

Maternally derived antibodies may have an
effect on efficacy of the vaccination.

Where the presence of maternally derived
antibodies is expected, the plan of vaccination
is needed to be adjusted in an appropriate
manner.

The tests of safety and efficacy have not been
performed in dwarf (pet) rabbits.

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

In the case of accidental self –injection seek
prompt medical advice and take the package
leaflet with you.

Pregnancy:

Can be used during pregnancy. It is not
recommended to vaccinate doe rabbits in the
last week of pregnancy due to hazard of
abortion following a strong grip.

Lactation:

Not applicable

Incompatibilities:

Do not mix with any other veterinary medicinal
product.

Interaction with other medicinal products and
other forms of interaction:

Safety and efficacy data are available and
demonstrate that vaccine Pestorin RHDV 2 can
be administered on the same day
simultaneously with the vaccine against
myxomatosis Myxoren. The vaccines should be
applied at separated sites. In the case of using
such concurrent application of the vaccines
complete mortality prevention has not been
demonstrated but reduced mortality against
RHDV2.

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.

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2019

15. OTHER INFORMATION

Packaging: 10 × 1 dose, 1 × 10 doses,
10 × 10 doses, 1 × 20 doses, 10 × 20 doses
Not all pack sizes may be marketed.

For animal treatment only.

Veterinary medicinal product subject to
prescription.

bioveta

Dimensions (mm):

Colours:

Prepared by:

Date:

A6 (105 × 148 mm) duplex printing

black

Hanáková

13. 01. 2022

Approved by:

Date: