LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated equine rotavirus H2 strain: RP ≥ 1.0 per 1 ml dose.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

3 x 1 ml
10 x 1 ml
20 x 1 ml
40 x 1 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

For vaccination of pregnant mares to provide passive transfer of antibodies to foals to reduce the risk of diarrhoea caused by equine rotavirus H2 strain.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

Pregnant mares should be given three doses of vaccine consisting of a single 1 ml dose administered intramuscularly at the 8th, 9th and 10th month of each pregnancy.

8. WITHDRAWAL PERIOD(S)

Withdrawal Period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4063

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection for horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated equine rotavirus H2 strain RP ≥ 1.0 per 1 ml dose

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Equip Rotavirus emulsion for injection for horses

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection for horses

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

Reddish/pinkish liquid.

Active substance:

Inactivated equine rotavirus H2 strain (7.4 x 106 to 7.4 x 107 FAID50**)	RP ≥ 1.0*

Adjuvants:
SP Oil Adjuvant:

Pluronic L121	1 mg
Squalane	1.6 mg
Tween 80 (Polysorbate 80)	0.17 mg
Phosphate buffered saline	to 0.05 ml.

* Product is blended based on pre-inactivation titre but the blended and finished product must have a relative potency of at least 1.0.

** Fluorescent antibody infectivity dose 50%.

4. INDICATION(S)

For vaccination of pregnant mares to provide passive transfer of antibodies to foals to reduce the risk of diarrhoea caused by equine rotavirus H2 strain.

Mares are able to transfer the passive immunity to the foals 4 weeks after the third vaccination. Foals of the vaccinated mares show an increase in antibodies against equine rotavirus for approximately sixty days.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In mares a transient increase (up to 1.8 °C) in rectal temperature which may last up to 2 days following vaccination may be very commonly observed.
A small visible soft to firm swelling (2.5 ≤ x ≤ 3.5 cm) lasting generally for only two days may be commonly observed. The swelling may be painful for 1–2 days.
In most cases these small and transient injection site reactions resolve with no need for treatment.

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 serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses (pregnant mares).

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

Intramuscular use

1.0 ml dose per mare to be administered by deep intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

Vaccination schedule
Pregnant mares should be given three doses of vaccine consisting of a single 1 ml dose administered at the 8th, 9th and 10th month of each pregnancy.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the syringe after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Use of this vaccine in a mare can only aid the control of diarrhoea associated with rotavirus in its foal when the foal receives an adequate quantity of colostrum, shortly after birth. Both the mare's ability to respond by the production of antibodies in colostrum and the ability of the foal to ingest and absorb that colostrum is required for the vaccine to have an effect.

Special precautions for use in animals:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

Pregnancy and lactation:
The vaccine can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

Interactions with other medicinal products and other forms of interaction:
No information is available on the compatibility of this vaccine when used with any other veterinary medicinal product. Therefore the safety and efficacy of this product when used with any other veterinary medicinal product (either when used on the same day or at different times) has not been demonstrated.

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

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

March 2020

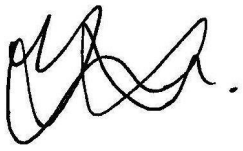
15. OTHER INFORMATION

For animal treatment only

Pack sizes:
Syringes are supplied in cardboard boxes of 3, 10, 20 and 40 units.
Not all pack sizes may be marketed.

ATC vet code: QI05AA09.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved: 05 June 2020