

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Carton Box 3 x 1
Dose, 10 x 1 Dose, 20 x 1 Dose, 40 x 1 Dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:

Equine rotavirus A, type G3P12, strain H2, inactivated: RP \geq 1.0.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Horses (pregnant mares).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

Read package leaflet before use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

14. MARKETING AUTHORISATION NUMBER

Vm 60021/3087

15. BATCH NUMBER

Lot{number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE
PACKAGING UNITS Syringe Label**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus.



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Equine rotavirus A, type G3P12, strain H2, inactivated RP \geq 1.0 per 1 ml dose.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equip Rotavirus emulsion for injection for horses

2. Composition

Each 1 ml dose contains:

Active substance:

Equine rotavirus A, type G3P12, strain H2, inactivated
(7.4×10^6 to 7.4×10^7 FAID₅₀**)

RP \geq 1.0*

* 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%.

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.

3. Target species

Horses (pregnant mares).



4. Indications for use

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. Special warnings

Special warnings:

Vaccinate healthy animals only.

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 within 24 hours after birth and a continuous intake of milk derived from the vaccinated mare is ensured. 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 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 leaflet or the label to the physician.

Pregnancy:

Can be used during pregnancy.

Lactation:

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.

Overdose:

Adverse events observed after administration of a double dose are similar to those following administration of a single dose as listed in section 7.

7. Adverse events

Horses (pregnant mares):

Very common (>1 animal / 10 animals treated):
Elevated temperature ¹
Common (1 to 10 animals / 100 animals treated):
Injection site pain ² , Injection site swelling ³

¹A transient increase (up to 1.8 °C) in rectal temperature which may last up to 2 days.

²At the swelling site. May last 1-2 days.

³A small visible soft to firm swelling ($2.5 \leq x \leq 3.5$ cm) lasting generally for only 2 days. In most cases these small and transient injection site reactions resolve with no need for treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

E-mail: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

8. Dosage for each species, routes and method of administration

Intramuscular use.

1 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 periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 60021/3087

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

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Dublin 18
D18 T3Y1
Ireland

Manufacturer responsible for batch release:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

17. Other information

POM-V