

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:

Equine rotavirus A, type G3P12, strain H2, inactivated RP $\geq 1.0^*$
(7.4×10^6 to 7.4×10^7 FAID₅₀**)

* 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	1.0 mg
Squalane	1.6 mg
Tween 80 (Polysorbate 80)	0.17 mg
Phosphate buffered saline	to 0.05 ml

Excipients:

Qualitative composition of excipients and other constituents
HEPES diluent:
Eagle's Earle's MEM growth medium
HEPES acid
Sodium hydrogen carbonate
Water for injections
Hydrochloric acid
Sodium hydroxide

Reddish/pinkish liquid

3. CLINICAL INFORMATION

3.1 Target species

Horses (pregnant mares).

3.2 Indications for use for each target species

For vaccination of pregnant mares to provide passive transfer of antibodies to foals to reduce the risk of diarrhoea caused by equine rotavirus type G3P12.

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.

3.3 Contraindications

None.

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

Lactation:

The safety of the veterinary medicinal product has not been established during lactation.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

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

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Adverse events observed after administration of a double dose are similar to those following administration of a single dose as listed in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA09

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

5.3 Special precautions for storage

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

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Single-dose type I glass syringes closed with bromobutyl rubber tips.

Syringes are supplied in cardboard packs of 3, 10, 20 and 40 units.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

To be completed nationally.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

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 }

B. 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 RP $\geq 1.0^*$
(7.4×10^6 to 7.4×10^7 FAID₅₀**)

*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

Reddish/pinkish liquid.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

To be completed nationally.

Syringes are supplied in cardboard boxes of 3, 10, 20 and 40 units.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
To be completed nationally.

Manufacturer responsible for batch release:

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

<Local representative <and contact details to report suspected adverse reactions>:>
To be completed nationally.