SUMMARY OF PRODUCT CHARACTERISTICS

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 ≥ 1.0*
(7.4×10^6 to 7.4×10^7 $FAID_{50}$**)

* 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.

Other precautions:
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]

[1]A transient increase (up to 1.8 °C) in rectal temperature which may last up to 2 days.
[2]At the swelling site. May last 1-2 days.

[3]A small visible soft to firm swelling (2.5 ≤ x ≤ 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 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 product 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

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/4063

8. DATE OF FIRST AUTHORISATION

05 September 2008

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

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 26 February 2025