SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Rotavirus emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Inactivated equine rotavirus H2 strain (serotype G3 P12) RP ≥ 1.0*
(7.4 x 106 to 7.4 x 107 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%.

Adjuvant:

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:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Reddish/pinkish liquid

4. CLINICAL PARTICULARS

4.1 Target species

Horses (pregnant mares)

4.2 Indications for use, specifying the 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 G3 P12 serotypes.

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.

4.3 Contraindications

None.

4.4 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 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.

4.5 Special precautions for use

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 leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

4.8 Interactions 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.

4.9 Amounts to be administered and administration route

Intramuscular use

1.0 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Adverse events observed after administration of a double dose are similar to those following administration of a single dose as listed in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Equidae, inactivated viral vaccines for horses.
ATC vet code: QI05AA09.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

HEPES diluent:
- Eagle's Earle's MEM growth medium
- HEPES acid
- Sodium hydrogen carbonate
- Water for injections
- Hydrochloric acid
- Sodium hydroxide

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Single-dose type I glass syringes (Ph. Eur. 3.2.1) closed with bromobutyl rubber tips (Ph. Eur. 3.2.9).
Syringes are supplied in cardboard packs of 3, 10, 20 and 40 units.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4063

9. DATE OF FIRST AUTHORISATION

05 September 2008

10. DATE OF REVISION OF THE TEXT

June 2020

Approved: 05 June 2020