SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:
Equine influenza virus strains:

A/equine-2/ South Africa/4/03	50 AU[1]
A/equine-2/ Newmarket/2/93	50 AU

[1] Antigenic units

Adjuvant:
Iscom-Matrix containing:

Purified Saponin	375 micrograms
Cholesterol	125 micrograms
Phosphatidylcholine	62.5 micrograms

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Clear opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

Active immunisation of horses from 6 months of age against equine influenza to reduce clinical signs and virus excretion after infection.

Influenza
Onset of immunity: 2 weeks after the primary vaccination course
Duration of immunity: 5 months after the primary vaccination course
12 months after the first revaccination

4.3 Contraindications

None.

4.4 Special warnings for each target species

Foals should not be vaccinated before the age of 6 months, especially when born to mares that were revaccinated in the last two months of gestation, because of possible interference by maternally derived antibodies.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

A diffuse hard or soft swelling (max. diameter 5 cm) may rarely occur at the injection site, regressing within 2 days. Pain at the injection site can occur in rare cases, which may result in temporary functional discomfort (stiffness). A local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur in very rare cases. Fever, sometimes accompanied by lethargy and inappetence, may in very rare cases occur for 1 day, and up to 3 days in exceptional circumstances.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Intramuscular use.

Allow the vaccine to reach room temperature before use.

Vaccination schedule:

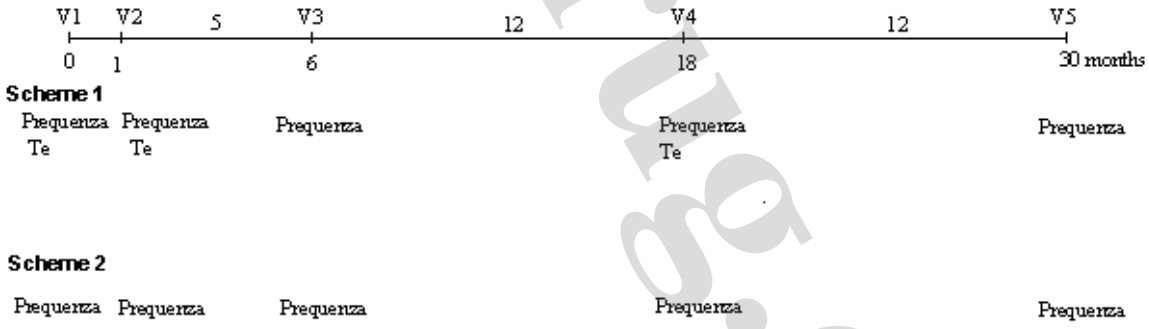
Primary vaccination course
Administer one dose (1 ml) strictly intramuscularly, according to the following schedule:
- Primary vaccination course: first injection from 6 months of age, second injection 4 weeks later.

Revaccination
It is recommended that a single booster dose should only be administered to horses that have already received a primary vaccination course using vaccines that contain the same types of equine influenza virus included in this vaccine. A primary vaccination course may be considered necessary in horses that have not been suitably primed.

The first revaccination (third dose) is given 5 months after the primary vaccination course. This revaccination results in immunity to equine influenza lasting at least 12 months.

The second revaccination is given 12 months after the first revaccination.

The alternate use, at 12 months interval, of a suitable vaccine against equine influenza, containing the strains A/equine-2/South Africa/4/03 and A/equine-2/Newmarket-2/93, is recommended to maintain immunity levels for the influenza component (see scheme).



In case of increased infection risk or insufficient colostrum intake, an additional initial injection can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 6 months of age and 4 weeks later).

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

Following the administration of a double dose of vaccine, no side-effects other than those described under section 4.6 have been observed except for some depression at the day of vaccination.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Equidae*, inactivated viral vaccines
ATCvet code: QI05AA01

To stimulate active immunity against Equine influenza in horses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphate buffer

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: 2 years.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vials of 1 ml (1 dose) closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.
Type I glass pre-filled syringes of 1 ml (1 dose), containing a plunger with a halogenobutyl end and closed with a halogenobutyl stopper.

Package sizes:
Cardboard box with 10 glass vials of 1 ml (1 dose).
Cardboard box with 1, 5 or 10 pre-filled syringes of 1 ml (1 dose) with needles.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

UK(GB):

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER(S)

UK(GB):
Vm 01708/5032

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 July 2005.
Date of last renewal: 27 July 2010.

10. DATE OF REVISION OF THE TEXT

11/2020.