

FOR ANIMAL USE ONLY

EQUILIS® PREQUENZA Te

Reg. No. G3774 (Act 36/1947)

Namibia Reg.No. V07/24.6/55 NS0

INDICATIONS

Equilis® Prequenza Te is indicated for the active immunisation of healthy horses and ponies against equine influenza. It reduces the severity and duration of clinical signs and reduces the amount and duration of viral shedding after infection. It is also indicated for the active immunisation against tetanus to prevent disease and mortality.

COMPOSITION

Equilis® Prequenza Te is a vaccine suspension containing per 1 ml:

• Purified haemagglutinin/neuraminidase subunits from equine influenza viruses:		
- A/equine-2/ South Africa/4/03	:	50 AU*
- A/equine-2/ Newmarket/2/93	:	50 AU
Tetanus toxoid	:	40 Lf**
Purified saponin (adjuvant)	:	375 µg

* Antigenic units

** Flocculation equivalents; corresponds with ≥ 30 IU/ml guinea pig serum in the Ph.Eur. potency test

STORAGE

- Store in the dark between 2 °C and 8 °C.
- Do not freeze.
- Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.
- Protect from direct sunlight.
- Keep the vial in the outer carton, in order to protect from light.

WARNINGS

- Vaccinate healthy animals only.
- Avoid intravenous injection.
- A transient swelling may occur after vaccination regressing within 2 days. In some cases fever may occur after vaccination.
- Do not mix **Equilis® Prequenza Te** with other vaccines, or administer another vaccine shortly before or after vaccination with this product.
- Accidental self-injection may lead to a severe local allergic reaction. Consult a physician immediately and show this package insert to the physician.
- Do not store partially used containers for future use and use the entire contents when opened.
- Dispose of any unused vaccine as well as all empty vaccine containers and vaccination equipment according to local waste disposal regulations.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this vaccine has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Observe aseptic conditions. Ensure that vaccination equipment (needles, syringes, etc.) is clean and sterile prior to and during use.

- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.
- Allow the vaccine to reach room temperature (15 °C to 25 °C) before use.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED.

Shake well before use.

Intramuscular injection of 1 dose (1 ml) per animal.

VACCINATION SCHEDULE

Influenza

Basic vaccination course

All horses not previously vaccinated should receive 2 vaccinations with a 4 week interval. The basic vaccination course results in immunity to equine influenza lasting at least 5 months. Foals should be vaccinated from the age of 6 months. If vaccination is performed before 6 months of age full protection can be expected after the third vaccination (first revaccination).

Revaccination

The first revaccination (third dose) is given 5 months after the basic vaccination course. The revaccination with **Equilis® Prequenza Te** or **Equilis® Prequenza** results in immunity to equine influenza for at least 12 months.

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

The alternate use, at 12 months interval, of **Equilis® Prequenza** is recommended to maintain immunity levels for the influenza component.

Local Regulations

Although **Equilis® Prequenza Te** or **Equilis® Prequenza** results in immunity for 12 months, local Jockey Club and Horse Society regulations should be adhered to. These often recommend a 6 month vaccine interval. In this case the alternate use of **Equilis® Prequenza Te** or **Equilis® Prequenza** is recommended.

Tetanus

Basic vaccination course

All horses not previously vaccinated should receive 2 vaccinations of 1 dose with a 4 week interval. The basic vaccination course results in immunity to tetanus for at least 17 months.

Revaccination

The first revaccination for tetanus can be given 17 months after the basic vaccination course. When a third injection with a vaccine containing tetanus is given at 5 months after basic vaccination, the next tetanus vaccination can be administered after 24 months.

In case of increased infection risk or insufficient colostrum intake, an initial injection can be given at the age of 4 months followed by a full vaccination programme.

Emergency vaccination

The vaccine can be used together with tetanus antiserum for the treatment of injured horses that have not been immunised against tetanus. In that case, the first dose of the basic vaccination can be combined with administration of the appropriate prophylactic dose of tetanus antiserum at a separate injection site. The second dose can be administered 4 weeks later as described above. It is recommended to repeat immunisation against tetanus after approximately 1 month.

PREGNANCY AND LACTATION

Can be used in pregnant mares, but handling of such animals, particularly in the latter stage of pregnancy, is not without risk and care should be taken to avoid stress.

PRESENTATION

Cardboard box with 10 x 1 mℓ glass vials or cardboard box with 1, 5 or 10 x 1 mℓ pre-filled syringes (needle enclosed).

REGISTRATION HOLDER

Intervet South Africa (Pty) Ltd.
20 Spartan Road, Spartan
1619, RSA
Tel: +27 (0) 11 923 9300
Fax: +27 (0) 11 392 3158
www.msd-animal-health.co.za

MANUFACTURER

Intervet International B.V.
35 Wim de Körverstraat
Boxmeer, The Netherlands

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