SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zylexis for Horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substance:

Inactivated parapoxvirus ovis, strain D1701 ≥ 1 RP*

* Relative Potency compared to a reference vaccine

Excipients:
Solvent:
Water for injections (WFI): q.s. 2 ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

Whitish coloured lyophilisate.
Clear and colourless solvent.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, from 10 months of age.

4.2 Indications for use, specifying the target species

Zylexis for horses acts by stimulation of the non-specific immune mechanisms and is of potential clinical value in the reduction of clinical signs of stress/crowding associated equine respiratory disease.

In a field study, reduction of clinical signs (defined as the first time-point at which significant differences were evidenced between groups) was shown on day 5 after administration of the full treatment schedule and lasted less than a week. This is a Limited Marketing Authorisation. A full set of supporting efficacy data is not available for this product.

4.3 Contraindications

None.

4.4 Special warnings for each target species

To ensure efficacy of the treatment, it is important that the first dose of the product is administered shortly before or up to the day of crowding or exposure to other stressful conditions. It is important that the complete treatment schedule of 3 doses is administered.

4.5 Special precautions for use

Special precautions for use in animals
The product should not be used for treatment of animals with chronic diseases with unclear causality.

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)

Hyperthermia associated with general malaise and musculoskeletal signs (stiffness, abnormal posture, tense muscle) have been observed very rarely in spontaneous reports.

Hypersensitivity reactions (i.e. circulatory shock, tachycardia, abdominal pain, convulsion) may occur very rarely. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening.

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

No information is available to support the use of the authorised schedule in pregnant mares. There is no information concerning safety in stallions.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product. A decision to use this product 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

Aseptically reconstitute the lyophilisate with the solvent provided. Shake well before use. The entire contents of the reconstituted vial should be administered intramuscularly as a single dose, irrespective of the body weight of the animal.

Dosage regimen
Three injections of a single dose for each animal are recommended.
The first two injections are administered with a 48-hours interval (day 0 and day 2) and the third injection should be administered on day 9.

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

In an overdose (4 ml) safety study carried out in horses, no systemic or local reactions were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The exact mechanism of action of inactivated parapoxvirus ovis is not fully understood but may involve the stimulation and increase of the non-specific immune mechanisms.
In a mouse model, it has been demonstrated that parapoxvirus ovis induces an autoregulatory cytokine response that involves the up regulation of T helper (Th) 1 type cytokines (IL-12, IL-18, IFNγ) and their subsequent down regulation which is accompanied by induction of IL-4. Furthermore, parapoxvirus ovis induces phagocytic activity and oxidative burst in various animal species including horses as demonstrated by *ex vivo* experiments.

In horses, it has been shown that administration of the product stimulates the proliferation of lymphocytes and increases the production of IFNγ *in vivo*.
It was also shown that administration of the product to horses increases the production of other cytokines such as TNFα, IFN β, IL15 and IL18 *in vivo*.

ATCvet code: QL03AX.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Casein hydrolysate
Dextran 40
Lactose
Sorbitol 70% (solution)
Sodium hydroxide
MEM with Earle’s Salts

Water for injections

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: 24 months.
Shelf life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type 1 glass vial, containing the lyophilisate (1 dose for horses) and type 1 glass vial, containing 2 ml of solvent.
Each vial is closed with a rubber stopper and sealed with an aluminium cap.

Pack sizes:
Boxes containing 1, 3, 5 or 6 glass vial(s) containing the lyophilisate together with 1, 3, 5 or 6 glass vial(s) of the solvent.
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, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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 42058/5208

9. DATE OF FIRST AUTHORISATION

23 April 2012

10. DATE OF REVISION OF THE TEXT

May 2025

Gavin Hall
Approved: 19 May 2025