A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zylexis for Horses, lyophilisate and solvent for suspension for Intramuscular injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated parapoxvirus ovis, strain D1701 ≥1 RP
Solvent

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

1 vial of lyophilisate and 1 vial of the solvent.
3 vials of lyophilisate and 3 vials of the solvent.
5 vials of lyophilisate and 5 vials of the solvent.
6 vials of lyophilisate and 6 vials of the solvent.

5. TARGET SPECIES

Horses from 10 months of age.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

In case of accidental self-injection, seek medical advice immediately – read package leaflet before use

10. EXPIRY DATE

EXP: {dd MMM yyyy}

Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Protect from light. Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.
POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4174

17. MANUFACTURER'S BATCH NUMBER

Batch No.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

Lyophilisate vial (2 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zylexis for Horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated parapoxvirus ovis, strain D1701

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 Intramuscular dose

4. ROUTE(S) OF ADMINISTRATION

<See point 3.>

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

Exp: {dd MMM yyyy}
Once reconstituted use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial (2 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zylexis for Horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

WFI

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 Intramuscular dose

4. ROUTE(S) OF ADMINISTRATION

<See point 3.>

5. WITHDRAWAL PERIOD

Withdrawal period: not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

Exp: {dd MMM yyyy}
Once reconstituted use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Zylexis for Horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zylexis for Horses

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Zylexis for Horses is a veterinary medicinal product presented as a lyophilisate and solvent for suspension for Intramuscular injection.

Each dose comprises:
One vial of lyophilised fraction containing inactivated parapoxvirus ovis, strain D1701 that generates a minimum of 1 RP * and one vial of water for injection.

*: Relative Potency compared to a reference vaccine.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet, please inform your veterinary surgeon.

All suspected adverse reactions and any suspected lack of efficacy should be reported to Zoetis UK Ltd technical helpline on 0845 300 8034.

7. TARGET SPECIES

Horses from 10 months of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 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-hour interval (day 0 and day 2) and the 3rd injection is administered on day 9.

9. ADVICE ON CORRECT ADMINISTRATION

Sterile needles and syringes should be used for administration.
Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect or sterilise skin.
Shake well before use.
Aseptic precautions should be observed.
Use immediately after reconstitution.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Do not freeze.
Shelf life after reconstitution according to directions: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

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.

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.

Pregnancy:
No information is available to support the use of the authorised schedule in pregnant mares.

Fertility:
There is no information concerning safety in stallions.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this 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.

Overdose (symptoms, emergency procedures, antidotes):
In an overdose (4 ml) safety study carried out in horses, no systemic or local reactions were observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

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, INFγ) 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*.

PACKAGE QUANTITIES
Boxes containing 1, 3, 5 or 6 glass vial(s) of lyophilisate together with 1, 3, 5 or 6 glass vial(s) of the solvent.

Not all pack sizes may be marketed.

LEGAL CATEGORY
For animal treatment only.
POM-V
To be supplied only on veterinary prescription.

MARKETING AUTHORISATION NUMBER

Vm 42058/4174

FURTHER INFORMATION
Further information on this product and its supporting data can be found on Veterinary Medicines Directorate (VMD) website product information database.

Approved: 08/04/21