ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carboard box – 8 x 2 ml. Contains blue box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:

Recombinant protein CCE from *Streptococcus equi*	≥ 111.8 micrograms*
Recombinant protein Eq85 from *Streptococcus equi*	≥44.6 micrograms*
Recombinant protein IdeE from *Streptococcus equi*	≥34.6 micrograms*

* as determined by means of in vitro potency tests (ELISA)

3. PHARMACEUTICAL FORM

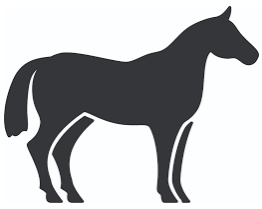
Suspension for injection

4. PACKAGE SIZE

8 x 1 dose

5. TARGET SPECIES

Horses and ponies



6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.
Shake the vial well before use. Avoid multiple vial broaching. Avoid introduction of contamination.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.

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.

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

Intervacc AB
Västertorpsvägen 135, Hägersten
129 44 Stockholm
Sweden

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52661/5000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial (1 dose)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

2 ml (1 dose)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Strangvac suspension for injection for horses and ponies

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

Marketing authorisation holder:
Intervacc AB
Västertorpsvägen 135, Hägersten
129 44 Stockholm
Sweden

Manufacturer responsible for batch release:
3P BIOPHARMACEUTICALS, S.L.
C/ Mocholí 2,
Polígono Industrial Mocholí,
Noáin,
Navarra,
31110,
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac suspension for injection for horses and ponies

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

One dose (2 ml) contains:

Active substances:

Recombinant protein CCE from *Streptococcus equi*	≥ 111.8 micrograms*
Recombinant protein Eq85 from *Streptococcus equi*	≥44.6 micrograms*
Recombinant protein IdeE from *Streptococcus equi*	≥34.6 micrograms*

* as determined by means of *in vitro* potency tests (ELISA)

Adjuvants:

Purified Quillaia saponin QS-21 (Fraction C)	≥260 micrograms
Cholesterol	
Phosphatidyl choline.	

Colourless to pale yellow suspension.

4. INDICATION(S)

Active immunisation of horses and ponies from 5 months of age for:

- Reduction of body temperature increase, coughing, inappetence, difficulty swallowing, and changes in demeanour in the acute stage of infection with *Streptococcus equi.*
- Reduction in number of abscesses within submandibular and retropharyngeal lymph nodes.

Onset of immunity: 2 weeks after the second vaccination dose.
Duration of immunity: 2 months after the second vaccination dose.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A transient increase in body temperature of up to 2.6 °C may occur very commonly and last for one to five days following vaccination. Transient local tissue reactions are very commonly seen at the injection site, characterised by heat, pain and swelling (up to 5 cm diameter), and last for up to five days. Prevalence of injection site reactions are more pronounced after the second primary dose or re-vaccinations including increased swelling of up to 8 cm diameter. Ocular discharge is very commonly seen, which may be mucopurulent and present from both eyes for one to five days after vaccination. Loss of appetite and demeanour changes are common for up to one day. Anaphylactic-like reactions occur in very rare cases.

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 or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and ponies

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

Intramuscular use.

Primary vaccination:
Administer one dose (2 ml) by intramuscular injection, followed by a second dose (2 ml) four weeks later.

Revaccination:
In horses at high risk of *S. equi* infections it is recommended to repeat the primary vaccination regimen after two months.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.
Keep the vial in the outer carton in order to protect from light.
Shelf life after first opening the immediate packaging: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Effect of vaccination on further stages of the infection, rupture of developed lymph node abscesses, prevalence of subsequent carrier status, bastard strangles (metastatic abscessation), purpura haemorrhagica and myositis and recovery, is not known.

Efficacy has been demonstrated for the individual horse to reduce clinical signs of disease in the acute stage of the infection. Vaccinated horses can be infected and shed *S. equi*.

Special precautions for use in animals:
No information is available on the use of the vaccine in seropositive animals, including those with maternally derived antibodies.
Biosecurity procedures to limit the risk of introduction and spread of *S. equi* infection in premises should be part of management tools.

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. An allergic reaction may occur. Treat symptomatically. Strangvac contains saponins, which have little toxicity for humans when ingested but have haemolytic effects when injected intravenously.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. In the absence of data, the use of this vaccine is not recommended.

Fertility:
The safety and efficacy of the vaccine has not been established in breeding males. The vaccine should be used only according to the benefit-risk assessment by the responsible veterinarian.

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.

Overdose (symptoms, emergency procedures, antidotes):
Not applicable

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

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

Medicines should not be disposed of via household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved 17 August 2022