SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac Suspension for Injection for Horses and Ponies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:

One dose (2 ml) contains:

Recombinant protein CCE from *Streptococcus equi*	≥ 111.8micrograms*
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.	

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Colourless to pale yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies

4.2 Indications for use, specifying the target species

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 of 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.

4.3 Contraindications

None.

4.4 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*.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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. Potential complications from vaccination and *S. equi* infection following challenge were not investigated.

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

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

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.

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.
Shake the vial well before use. Avoid multiple vial broaching. Avoid introduction of contamination.
It is recommended that all horses and ponies in a stable are vaccinated.

Vaccination schedule:
Primary vaccination course:
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.

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

Not applicable

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for *Equidae*, inactivated bacterial vaccines for horses.
ATCvet code: QI05AB01 – streptococcus.

The vaccine contains recombinant protein antigens derived from *Streptococcus equi*, which are not living and cannot spread to other animals. Strangvac stimulates active immunity against *Streptococcus equi,* the causative agent of strangles in horses. After vaccination, in addition to antibodies in the blood, local antibodies (IgG) can also be detected in secretions from the nasal passages. The immunogenicity of the *Streptococcus equi* antigens is enhanced by ISCOM (Immune Stimulating COMplex). Based on measured antibody titers immunological memory response was found in horses following repeated vaccination 6 months after primary vaccination. The role of the measured antibodies in the immune response relevant for the protection against strangles is not known.
Strangvac does not contain the DNA targets of diagnostic qPCR tests for *Streptococcus equi* or the A and C antigens used in the iELISA diagnostic test for exposure to *Streptococcus equi*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Quillaia saponin QS-21 (Fraction C)
Cholesterol
Phosphatidyl choline
Sodium chloride
Trometamol
Polysorbate 80
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: 33 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type I glass vial closed with a bromobutyl rubber stopper and sealed with a white aluminium crimp cap.

Package size:
Cardboard box with 8 vials of 1 dose (2 ml).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

Intervacc AB

Västertorpsvägen 135, Hägersten

SE -129 44 Stockholm

Sweden

8. MARKETING AUTHORISATION NUMBER

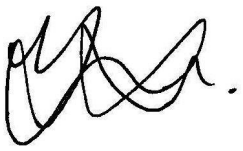
Vm 52661/5000

9. DATE OF FIRST AUTHORISATION

17 September 2021

10. DATE OF REVISION OF THE TEXT

May 2023



Approved: 05 May 2023