

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

4.2 Indications for use, specifying the target species

For active immunisation of horses from 8 months of age for:

- Reduction of body temperature increase, coughing, difficulty swallowing, and signs of depression (inappetence, 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

The vaccine is intended for use in horses for which a high risk of *Streptococcus equi* infection has been clearly identified from areas where this pathogen is known to be present.

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*.

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, regardless of vaccination with this product.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine is tested safe for use in horses from the age of 5 months.

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.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in body temperature of up to 2.6°C for one to five days is very common following vaccination.

Transient local tissue reactions at the injection site, characterised by heat, pain and swelling (approximately 5 cm diameter) are very commonly seen and last for up to five days. Frequency of injection site reactions are more pronounced after the second primary dose and further doses and increased swelling of up to 8 cm diameter can occur.

Loss of appetite and demeanour changes for one day are common.

Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination.

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 reactions)
- 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, 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. 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 animals. 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.

Vaccination schedule:

Primary vaccination course:

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

Re-vaccination:

Data for prolonged clinical immunity from the administration of single dose revaccinations are not available. Therefore, 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: immunological for *Equidae*, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), *Streptococcus*.

ATCvet code: QI05AB01

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).

Efficacy of vaccination was demonstrated in studies using an experimental challenge model of the acute stage of the infection with the heterologous strain, *Streptococcus equi* 4047 (isolated in New Forest, UK in 1990).

After challenge (two weeks and two months after the second dose of vaccine), vaccinated horses demonstrated reduced acute clinical signs compared to unvaccinated controls.

Of the vaccinated animals,

- 43% (12 out of 28 ponies) remained pyrexia free (pyrexia defined as 39.0°C or above for two out of three days). The number of days with pyrexia was significantly lower in the vaccinated compared to non-vaccinated animals.
- 36% (10 out of 28) did not show signs of coughing.
- 43% (12 out of 28 ponies) did not show signs of difficulty in swallowing.
- 43 % (12 out of 28) did not show signs of marked depression (inappetence, marked change in demeanour) after challenge.

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.

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: 2 years.
 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
Vastertorpsvagen 135
129 44 Hagersten
SWEDEN

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/274/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C STATEMENT OF THE MRLs**

A MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufactures of the biological active substances

3P BIOPHARMACEUTICALS, S.L.
C/ Mocholí 2,
Polígono Industrial Mocholí,
Noáin,
Navarra,
31110,
SPAIN

Name and address of the manufacturer responsible for batch release

3P BIOPHARMACEUTICALS, S.L.
C/ Mocholí 2,
Polígono Industrial Mocholí,
Noáin,
Navarra,
31110,
SPAIN

B CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box – 8 x 2 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Recombinant proteins from *Streptococcus equi*

3. PHARMACEUTICAL FORM

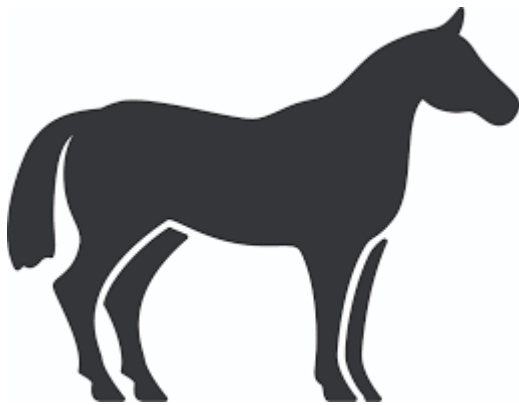
Suspension for injection

4. PACKAGE SIZE

8 x 1 dose

5. TARGET SPECIES

Horse



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**10. EXPIRY DATE**

EXP {month/year} Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C - 8°C).

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
Vastertorpsvagen 135
129 44 Hagersten
SWEDEN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/274/001

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Strangvac vial label, 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Strangvac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Recombinant proteins from *Streptococcus equi*

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

2 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP {month/year}

Once broached use immediately.

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
Vastertorpsvagen 135
129 44 Hagersten
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

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

One dose (2 ml) contains:

Active substances:

Recombinant protein CCE from <i>Streptococcus equi</i>	≥ 111.8 micrograms
Recombinant protein Eq85 from <i>Streptococcus equi</i>	≥ 44.6 micrograms
Recombinant protein IdeE from <i>Streptococcus equi</i>	≥ 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 yellow clear suspension.

4. INDICATION(S)

For active immunisation of horses from 8 months of age for:

- Reduction of body temperature increase, coughing, difficulty swallowing, and signs of depression (inappetence, 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

The vaccine is intended for use in horses for which a high risk of *Streptococcus equi* infection has been clearly identified from areas where this pathogen is known to be present.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A transient increase in body temperature of up to 2.6°C for one to five days is very common following vaccination.

Transient local tissue reactions at the injection site, characterised by heat, pain and swelling (approximately 5 cm diameter) are very commonly seen and last for up to five days. Frequency of injection site reactions are more pronounced after the second primary dose and further doses and increased swelling of up to 8 cm diameter can occur.

Loss of appetite and demeanour changes for one day are common.

Ocular discharge which may be mucopurulent and present from both eyes is very commonly seen for one to five days after vaccination.

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 reactions)
- 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, 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.

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

Intramuscular use.

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

Vaccination schedule:

Primary vaccination course:

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

Re-vaccination:

Data for prolonged clinical immunity from the administration of single dose revaccinations is not available.

Therefore, 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 hemorrhagica 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*.

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, regardless of vaccination with this product.

Special warnings for use in animals:

The vaccine is tested safe for use in horses from the age of 5 months.

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.

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>

15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.