ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE, lyophilisate and solvent for suspension for injection, for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.2 ml vaccine:

Active substance:

Live deletion mutant *Streptococcus equi* strain TW928 $10^{9.0}$ to $10^{9.4}$ cfu[1]

[1]colony forming units

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

Lyophilisate: off-white or cream-coloured pellet
Solvent: clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

For immunisation of horses against *Streptococcus equi* to reduce clinical signs and occurrence of lymph node abscesses.

Onset of immunity: 2 weeks after basic vaccination.

Duration of immunity: up to 3 months.

The vaccine is intended for use in horses for which a risk of *Streptococcus equi* infection has been clearly identified, due to contact with horses from areas where this pathogen is known to be present, e.g. stables with horses that travel to shows and/or competitions in such areas, or stables that obtain or have livery horses from such areas.

4.3 Contraindications

None.

4.4 Special warnings

Shedding of the vaccine strain from the injection site can be observed for a period of four days after vaccination.

From literature, it is known that a very low number of horses may develop purpura haemorrhagica if they are vaccinated shortly after infection. Purpura haemorrhagica has not been observed in any of the safety studies performed during development of Equilis StrepE. As the incidence of purpura haemorrhagica is very low, its occurrence cannot be ruled out completely.

In the challenge studies performed by the company, insufficient protection was seen in approximately one quarter of horses vaccinated with the recommended dose.

Do not use antibiotics within one week after vaccination.

The vaccine strain is sensitive to penicillins, tetracyclines, macrolides and lincomycin.

The vaccine strain is resistant to aminoglycosides, sulphonamides, flumequine and trimetroprim-sulfa combinations.

4.5 Special precautions for use

Special precautions for use in animals

Only healthy horses should be vaccinated.

Ensure that the lyophilisate is completely reconstituted before use.

Basic vaccination performed during an outbreak is not efficacious, because immunity is insufficient until basic vaccination has been completed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This product contains a live bacterial deletion mutant with a limited growth potential in mammalian tissue. Accidental self-injection may result in an inflammatory reaction with severe pain and swelling. Special care must be taken when connecting the applicator to the needle to avoid needle-stick injuries. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician even if only a very small amount is injected.

To the physician:
This product contains a live auxotrophic deletion mutant *Streptococcus equi* vaccine strain with attenuated virulence. However, the bacterial compounds of this product can cause an inflammatory reaction with intense and painful swelling after accidental injection.
Anti-inflammatory therapy is indicated even if only a very small amount of the product in injected. An additional antibiotic treatment should be considered for safety reasons. The sensitivity of the vaccine strain to antibiotics is listed above (under section 4.4).

4.6 Adverse reactions (frequency and seriousness)

After vaccination a diffusely swollen reaction, which may be warm or painful, develops at the injection site within 4 hours. The reaction is maximal at 2–3 days post vaccination with a maximum area of 3 cm by 8 cm. This swelling resolves completely within 3 weeks and normally has no effect on the appetite of the vaccinated animal and causes no apparent discomfort. The vaccine organism may establish a small suppurative inflammation locally at the injection site, leading to a disruption of the overlaying lip mucosa and subsequent discharge fluid and inflammatory cells. A slight cloudy discharge commonly occurs from the mucosal injection site at 3 or 4 days post vaccination.

Slight enlargements, which may be transient painful, of the retropharyngeal and mandibular lymph nodes may occur for a few days after vaccination. In very rare cases an abscess may develop at the injection site or in the regional lymph nodes.

Further, an increase in rectal temperature up to 2 °C may occur on the day of vaccination. In rare cases, inappetence, fever, shivering and diffuse oedematous swellings (e.g. facial oedema, swollen muzzle/upper lip) may be observed. In very rare cases depression may develop.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating mares.

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

Submucosal vaccination with 0.2 ml of reconstituted product.

Vaccination scheme:
Basic vaccination: horses from 4 months of age onwards receive two vaccinations of one dose with a 4 week interval.

Revaccination:
Revaccinate every three months to maintain immunity.

A priming response is maintained for up to six months after basic vaccination. Therefore only a single dose of vaccine is needed to restore immunity.

It is recommended that all horses stabled together are vaccinated.

Allow the sterile solvent to reach room temperature (15–25 °C). Aseptically reconstitute the lyophilisate with 0.3 ml of the sterile solvent provided. Allow the reconstituted vaccine to sit for 1 minute and then carefully swirl the contents to mix. Do NOT shake. Withdraw 0.2 ml of the reconstituted vaccine into the syringe provided (see Figure 1) and connect the applicator to the needle (see Figure 2). Restrain the animal's head, lift the upper lip and insert the needle into the inside of the upper lip until the applicator rests on the lip. Administer the whole contents of the syringe into the inside of the upper lip (see Figure 3).

Figure 1

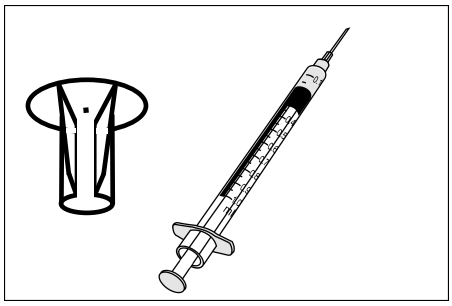


Figure 2

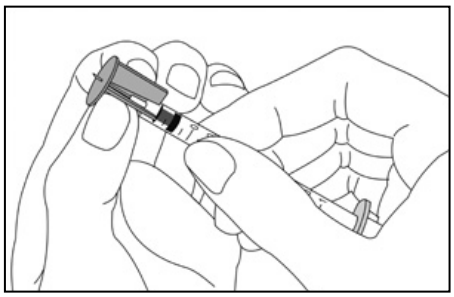
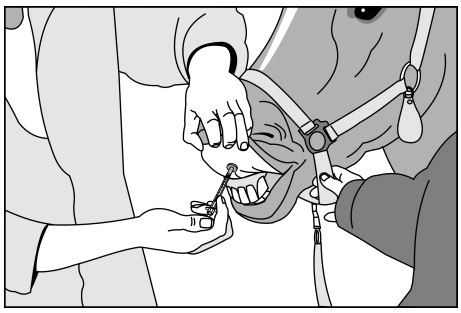


Figure 3



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

In addition to the clinical signs given under section 4.6, vaccination with a ten times overdose may induce an abscess in one of the submandibular lymph nodes. The abscesses drain purulent material from 2 weeks after vaccination, but heal without intervention within a month thereafter. Furthermore, an increase in rectal temperature up to 2.5 °C may occur on the day of vaccination. Slight apathy may occasionally be observed one day after vaccination.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunological for equidae, live bacterial vaccine,
ATCvet code: QI05AE.

To stimulate immunity against *Streptococcus equi*.

The vaccine strain is a deletion mutant with a limited growth potential in mammalian tissue. It is able to multiply locally at the submucosal injection site during a short period and is shed into the oro-nasal cavity during a few days, but the vaccine strain does not survive on the oro-nasal mucosa and does not disseminate systemically at the recommended dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

NAO-1 stabiliser
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products except the solvent supplied for use with the vaccine.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after reconstitution according to directions: 4 hours.

6.4 Special precautions for storage

Lyophilisate:
Store in a refrigerator (2 °C – 8 °C). Protect from light.
Solvent:
This medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Each package of Equilis StrepE contains: 10 vials with lyophilisate and 10 vials of 0.5 ml solvent, each in 3 ml Type I glass vials closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap, 10 applicators, 10 syringes with needle.

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

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/043/001

9. DATE OF FIRST AUTHORISATION

Date of first authorization: 07.05.2004
Date of last renewal: 10.04.2014

10. DATE OF REVISION OF THE TEXT

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 manufacturer of the biological active substance
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer
The Netherlands

Name and address of the manufacturer responsible for batch release
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer
The Netherlands

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 produce 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 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

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE, lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE

0.2 ml dose:
Live deletion mutant *Streptococcus equi* strain TW928 $10^{9.0}$ to $10^{9.4}$ cfu

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. PACKAGE SIZE

10 x 1 dose of vaccine
10 x 1 dose of solvent
10 applicators
10 syringes with needle

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration submucosally to the inside of the upper lip.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
After reconstitution use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C). Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/043/001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE INNER BOX WITH LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE, lyophilisate for suspension for injection, for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCE

0.2 ml dose:
Live deletion mutant *Streptococcus equi* strain TW928 $10^{9.0}$ to $10^{9.4}$ cfu

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. PACKAGE SIZE

10 x 1 dose

5. TARGET SPECIES

Horses

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNINGS

10. EXPIRY DATE

Exp {month/year}
After reconstitution use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store refrigerated (2 °C – 8 °C). Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE INNER BOX WITH SOLVENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE – solvent

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

10 x 1 dose

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE

2. QUANTITY OF THE ACTIVE SUBSTANCE

Live *Streptococcus equi*.

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

1 dose

4. ROUTE OF ADMINISTRATION

For submucosal use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

Exp: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS ON IMMEDIATE PACKAGING OF THE SOLVENT

Solvent vial

1. NAME OF THE DILUENT

Equilis StrepE – solvent

2. CONTENTS BY WEIGHT, BY VOLUME OR BYNUMBER OF DOSES

1 dose

3. ROUTE OF ADMINISTRATION

See package leaflet.

4. STORAGE CONDITIONS

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equilis StrepE, lyophilisate and solvent for suspension for injection, for horses

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

Marketing authorization holder and manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis StrepE, lyophilisate and solvent for suspension for injection, for horses

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

Per dose of 0.2 ml vaccine:
Live deletion mutant *Streptococcus equi* strain TW928 $10^{9.0}$ to $10^{9.4}$ cfu[1]

[1]colony forming units

Lyophilisate: off-white or cream coloured pellet
Solvent: clear colourless solution

4. INDICATION(S)

For immunisation of horses against *Streptococcus equi* to reduce clinical signs and occurrence of lymph node abscesses.

The onset of immunity is established as two weeks after vaccination. The duration of immunity is up to 3 months.

The vaccine is intended for use in horses for which a risk of *Streptococcus equi* infection has been clearly identified, due to contact with horses from areas where this pathogen is known to be present, e.g. stables with horses that travel to shows and/or competitions in such areas, or stables that obtain or have livery horses from such areas.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

After vaccination a diffusely swollen reaction, which may be warm or painful, develops at the injection site within 4 hours. The reaction is maximal at 2–3 days post vaccination with a maximum area of 3 cm by 8 cm. This swelling resolves completely within 3 weeks and normally has no effect on the appetite of the vaccinated animal and causes no apparent discomfort. The vaccine organism may establish a small suppurative inflammation locally at the injection site, leading to a disruption of the

overlaying lip mucosa and subsequent discharge fluid and inflammatory cells. A slight cloudy discharge commonly occurs from the mucosal injection site at 3 or 4 days post vaccination.

Slight enlargements, which may be transient painful, of the retropharyngeal and mandibular lymph nodes may occur for a few days after vaccination. In very rare cases an abscess may develop at the injection site or in the regional lymph nodes.
Further, an increase in rectal temperature up to 2 °C may occur on the day of vaccination. In rare cases, inappetence, fever, shivering and diffuse oedematous swellings (e.g. facial oedema, swollen muzzle/upper lip) may be observed. In very rare cases depression may develop.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Submucosal vaccination of 0.2 ml of reconstituted product.

Basic vaccination: Horses from 4 months of age onwards receive two vaccinations of one dose with a 4 week interval.

Revaccination: Revaccinate every three months to maintain immunity.

A priming response is maintained for up to six months after basic vaccination. Therefore only a single dose of vaccine is needed to restore immunity.

It is recommended that all horses stabled together are vaccinated.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the sterile solvent to reach room temperature (15–25 °C). Aseptically reconstitute the freeze-dried vaccine with 0.3 ml of the sterile solvent provided. Allow the reconstituted vaccine to sit for 1 minute and then carefully swirl the contents to mix. Do NOT shake. Withdraw 0.2 ml of the reconstituted vaccine into the syringe provided with the vaccine (see Figure 1) and connect the applicator to the needle (see Figure 2). Restrain the animal's head, lift the upper lip and insert the needle into the inside of the upper lip until the applicator rests on the lip. Administer the whole contents of the syringe into the inside of the upper lip (see Figure 3).

Figure 1

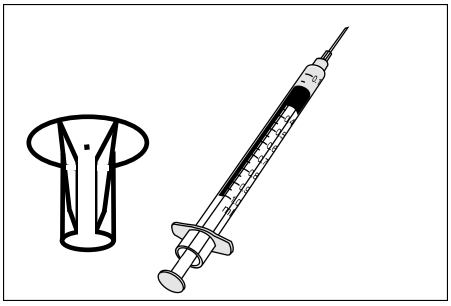


Figure 2

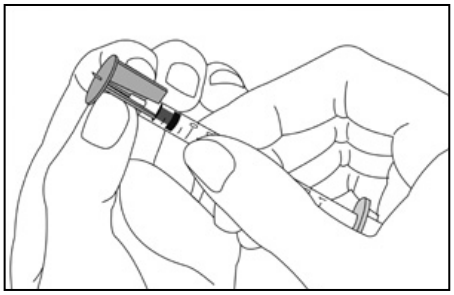
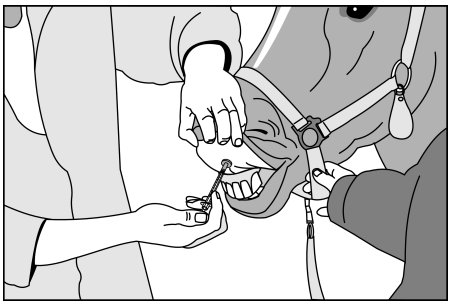


Figure 3



10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and reach of children.
Lyophilisate: Store in a refrigerator (2 °C – 8 °C). Protect from light.
Solvent: This medicinal product does not require any special storage conditions.
Shelf life after reconstitution according to directions: 4 hours.

12. SPECIAL WARNINGS

Special warnings:
Shedding of the vaccine strain from the injection site can be observed for a period of four days after vaccination.

From literature, it is known that a very low number of horses may develop purpura haemorrhagica if they are vaccinated shortly after infection. Purpura haemorrhagica has not been observed in any of the safety studies performed during development of Equilis StrepE. As the incidence of purpura haemorrhagica is very low, its occurrence cannot be ruled out completely.

In the challenge studies performed by the company, insufficient protection was seen in approximately one quarter of horses vaccinated with the recommended dose.

Do not use antibiotics within one week after vaccination.

The vaccine strain is sensitive to penicillins, tetracyclines, macrolides and lincomycin.

The vaccine strain is resistant to aminoglycosides, sulphonamides, flumequine and trimetroprim-sulfa combinations.

Special precautions for use in animals
Only healthy horses should be vaccinated.

Ensure that the lyophilisate is completely reconstituted before use.

Basic vaccination performed during an outbreak is not efficacious, because immunity is insufficient until basic vaccination has been completed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This product contains a live bacterial deletion mutant with a limited growth potential in mammalian tissue. Accidental self-injection may result in an inflammatory reaction with severe pain and swelling. Special care must be taken when connecting the applicator to the needle to avoid needle-stick injuries. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician even if only a very small amount is injected.

To the physician:
This product contains a live auxotrophic deletion mutant *Streptococcus equi* vaccine strain with attenuated virulence. However, the bacterial compounds of this product can cause an inflammatory reaction with intense and painful swelling after accidental injection.
Anti-inflammatory therapy is indicated even if only a very small amount of the product in injected. An additional antibiotic treatment should be considered for safety reasons. The sensitivity of the vaccine strain to antibiotics is listed above.

Use during pregnancy, lactation or lay:
Do not use in pregnant or lactating mares.

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):
In addition to the clinical signs given under section 6, vaccination with a ten times overdose may induce an abscess in one of the submandibular lymph nodes. The abscesses drain purulent material from 2 weeks after vaccination, but heal without intervention within a month thereafter. Furthermore, an increase in rectal temperature up to 2.5 °C may occur on the day of vaccination. Slight apathy may occasionally be observed one day after vaccination.

Incompatibilities:
Do not mix with any other veterinary medicinal products except the solvent supplied for use with the vaccine.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

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 animal treatment only.

10 x 1 dose of vaccine
10 x 1 dose of solvent
10 applicators
10 syringes with needle

The vaccine strain is a deletion mutant with a limited growth potential in mammalian tissue. It is able to multiply locally at the submucosal injection site during a short period and is shed into the oro-nasal cavity during a few days, but the vaccine strain does not survive on the oro-nasal mucosa and does not dissiminate systemically at the recommended dose.

For any information about this veterinary medicinal product, please contact the marketing authorization holder.