CHARACTERISTICS OF VETERINARY MEDICINAL PRODUCT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STREPTOVAC, emulsion for injections for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF THE ACTIVE SUBSTANCES

Inactivated antigens of *Streptococcus suis:*
serotype 2, concentration before inactivation minimum 8.5 x 10^8 cfu/dose
serotype 1/2, concentration before inactivation minimum 8.5 x 10^8 cfu/dose

3. PHARMACEUTICAL FORM

Emulsion for injections

4. CLINICAL PARTICULARS

4.1. Target animal species

Pig

4.2. Therapeutic indications for particular animal target species

Active immunisation of piglets in order to decrease mortality, clinical symptoms and/or lesions caused by the bacteria *Streptococcus suis.*
Immunity is acquired within two weeks after the administration of the vaccine.
The degree of the immunity depends primarily on proper feeding and zoohygienic conditions.

4.3. Contraindications

Do not use in sick animals.

4.4. Special warnings for use in each target animal species

Not available.

4.5. Special precautions for use, including special precautions for people who administer this veterinary medicinal product to animals

In case of accidental self-injection, immediately seek medical attention and show this information leaflet or the packaging to the physician.

4.6. Adverse events

Within a few hours after the administration of the preparation, internal temperature may rise by 2°C. The temperature returns to a normal value without undertaking treatment. An inflammatory condition, which recedes spontaneously, may arise at the vaccine injection site.

4.7. Use during gestation, lactation or laying period

Safety of the veterinary medicinal product used during gestation and lactation has not been determined.

4.8. Interactions with other medicinal products or other types of interactions

No information on the safety and efficacy of this vaccine when used simultaneously with other veterinary medicinal product is available. The decision to use the vaccine before or after the administration of any other veterinary medicinal product should be made individually.

4.9. Dosage and route(s) of administration for each target animal species

The preparation is administered twice at the interval of 2-3 weeks in a 2-ml dose.
The preparation is administered to piglets shortly before weaning and 2 to 3 weeks later, in a 2-ml dose, intramuscularly in the neck area.
Sterile needles and syringes should be used for the vaccinations.
Before the beginning of the vaccinations, transfer the preparation into room temperature and mix the content of the bottle directly before the injection.

4.10. Overdose (including its symptoms, course of conduct when rendering immediate aid and antidotes), if necessary

On the administration of the double dose of the vaccine, no adverse events have been observed.

4.11. Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological preparations for Suidae
ATCvet code: QI09AB
The product contains inactivated cells of the serotypes 2 and 1/2 of *Streptococcus suis*, which are immunogenic antigens that induce immunity against streptococcosis caused by the above serotypes. Due to the lack of cross-immunity following the vaccination with different strains of *Streptococcus suis*, the vaccine should be used only in such cases where the cause of morbidity is the type 2 or/and 1/2.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Gel of aluminium hydroxide
Water-oil emulsion

6.2. Major pharmaceutical incompatibilities

Since no incompatibility studies have been conducted, this veterinary medicinal product must not be combined with other veterinary medicinal products.

6.3. Shelf-life

1 year for the veterinary medicinal product packaged for sale.

Shelf-life after the first opening of the immediate packaging − 1 day.

6.4. Special precautions for storage and transport

Store in a refrigerator (from +2 to +8°C). Protect from light. Do not freeze.

6.5. Type of the packaging and its material composition

Glass bottles (hydrolytic class II) secured with a rubber stopper and an aluminium cap containing 50 or 100 ml of the vaccine, packed individually in a cardboard box. Some pack sizes may not be available in stock.

6.6. Special precautions for disposal of the unused veterinary medicinal product and wastes derived from this product, if applicable

Any unused veterinary medicinal product or waste materials derived from this product should be disposed of in accordance with applicable regulations.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Biowet Puławy Ltd .
24 - 100 Puławy, ul. Arciucha 2

8. NUMBER OF THE MARKETING AUTHORISATION

9. DATE OF ISSUE OF THE FIRST MARKETING AUTHORISATION / RENEWAL DATE OF THE MARKETING AUTHORISATION

10. DATE OF THE LAST REVISION OF THIS CHARACTERISTICS OF THE VETERINARY MEDICINAL PRODUCT

PROHIBITION OF SALE, SUPPLY AND/OR USE, IF APPLICABLE

Not applicable