SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:
- Inactivated lysed antigen concentrate of *Erysipelothrix rhusiopathiae* strain M2 (serotype 2): ≥ 1 pig protective dose (ppd)*
- Inactivated porcine parvovirus (PPV) strain 014: ≥ 552 EU**

* as measured in the Ph. Eur. potency test
** as determined in the final product by antigenic mass ELISA

Adjuvant:
dl-α-tocopherol: 150 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Aqueous white or nearly white liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use, specifying the target species

For active immunisation of sows and gilts to prevent clinical signs of Erysipelas disease caused by all relevant *Erysipelothrix rhusiopathiae* serotypes (serotype 1 and 2) and for protection against embryonal and foetal death caused by porcine parvovirus (PPV) infection.

E. rhusiopathiae:
Onset of immunity: 3 weeks.
Duration of immunity: 6 months.

Porcine parvovirus (PPV):
Duration of immunity: 12 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Sick and weak animals should not be vaccinated.

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 label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies and field trials
Transient increases in body temperature (0.5 °C) within 24 hours may very commonly occur.
Mild transient local swelling (Ø 1 – 10 mm) until 8 days after vaccination may very commonly occur.
Transient reluctance to move may commonly occur.

In post marketing experience
In very rare cases, a hypersensitivity reaction may occur.

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

Can be used during pregnancy and lactation.

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

Administer one dose of 2 ml by deep intramuscular injection behind the ear.

Before use, allow the vaccine to reach room temperature. Shake well before and regularly during use.
Use sterile vaccination equipment. Avoid introduction of contamination by multiple broaching.

Primary vaccination course:
Protection against *E. rhusiopathiae* and PPV should be achieved in gilts before first mating.
To induce protection against erysipelas, a double vaccination as a primary vaccination course is advised. This can be achieved with the monovalent erysipelas vaccine (Porcilis Ery) either 4 weeks before or 4 weeks after use of this combined erysipelas and PPV vaccine.
A single injection not later than 2 weeks before mating is sufficient to protect the following pregnancy from damage due to PPV.
To avoid possible interference from maternal antibodies the pigs should be 6 months old before vaccination to ensure efficacy against PPV.

Revaccinations:
Revaccinations should be administered once a year, supplemented with the administration of the monovalent erysipelas vaccine (Porcilis Ery), 6 months after use of this combined erysipelas and PPV vaccine.

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

Reactions observed after administration of a double dose are not different from those observed after administration of a single dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL01.

The active substances are a lysate of *E. rhusiopathiae* strain M2 (serotype 2) and inactivated porcine parvo virus strain 014.
For the active immunisation of sows and gilts, as an aid in the control of swine erysipelas and for the protection of their embryos and foetuses against porcine parvovirus infection.
The antigens are incorporated in an aqueous tocopherol-based adjuvant in order to enhance a prolonged stimulation of immunity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Tris (hydroxymethyl) aminomethane
Sodium chloride
Simethicone
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: 10 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

PET-vial closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
1 vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses) packed in a cardboard box.
Not all pack sizes may be marketed.

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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

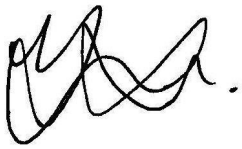
Vm 01708/4334

9. DATE OF FIRST AUTHORISATION

16 July 1997

10. DATE OF REVISION OF THE TEXT

November 2020



Approved: 26 November 2020