

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Progressis emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Inactivated porcine reproductive and respiratory syndrome virus, type 1,
P120 strain $\geq 2.5 \log_{10}$ IF* units.

*IF units: ImmunoFluorescence antibody titre obtained after 2 injections in pigs under specific laboratory conditions.

Adjuvant:

O/w oily excipient (containing hydrogenated polyisobutene as adjuvant) q.s. 1 dose of 2 ml.

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Polyoxyethylene fatty acids	
Ether of fatty alcohols and of polyols	
Benzyl alcohol	
Triethanolamine	
Potassium chloride	
Sodium chloride	
Potassium dihydrogen phosphate	
Disodium phosphate dihydrate	
Magnesium chloride	
Calcium chloride	
Water for injections	

White homogeneous emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (sows and gilts).

3.2 Indications for use for each target species

Reduction of the reproductive disorders caused by porcine reproductive and respiratory syndrome virus (European strain) in a contaminated environment: vaccination reduces the number of early farrowings and the number of still-births.

Onset of immunity: has not been established

Duration of immunity: has not been established

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

In PRRS infected herds, viral infection is heterogeneous and varies over time. In such context, the implementation of a vaccination program is a tool to improve the reproductive parameters and may contribute to the disease control in conjunction with sanitary measures.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (sows and gilts).

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction ¹
Very rare	Injection site oedema ² , Injection site granuloma ³

¹In such cases, an appropriate symptomatic treatment should be carried out.

²Oedema (at most 3 cm) lasting generally less than one week.

³Small local reaction (granulomas), without any effect on the health and the reproductive performance of the animal.

Larger reactions (up to 7 cm diameter) have been observed occasionally after frequently repeated revaccinations.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Data are available which demonstrate that this vaccine can be administered on a same day in a separate site, with inactivated vaccines against parvovirus, influenza and Aujeszky's disease as no adverse effect on the serological response has been observed.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

3.9 Administration routes and dosage

One dose of 2 ml is administered by deep intramuscular route, in the neck muscles behind the ear, according to the following vaccination scheme:

Primary vaccination:

Gilts:

2 injections 3-4 weeks apart, at least 3 weeks before mating.

Sows:

2 injections 3-4 weeks apart (vaccination of all the sows of the herd within a short period is recommended).

Revaccination:

One injection at 60-70 days of each gestation, as of the first gestation following the primary vaccination.

Shake well before use.

Apply usual aseptic procedures.

The use of a multi-dosing syringe is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of a double dose, no adverse reactions other than those described in section 3.6 were observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AA05

The vaccine contains inactivated PRRS virus in an oily adjuvant. It is intended to stimulate immunity against PRRS virus. The efficacy was demonstrated under field conditions during field trials. Whereas no effector immunomechanism on protection has been shown, the uptake of the vaccine has been demonstrated by the production of specific anti-PRRS IF antibodies in vaccinated animals.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

Do not freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:

- Type I glass bottle, LDPE bottle
- Nitril elastomer closure
- Aluminium cap

Packaging intended for sale:

- Box of 1 bottle of 5 doses / 10 ml glass bottle
- Box of 10 bottles of 5 doses / 10 ml glass bottle
- Box of 1 bottle of 10 doses / 20 ml glass bottle
- Box of 10 bottles of 10 doses / 20 ml glass bottle
- Box of 1 bottle of 25 doses / 50 ml glass bottle
- Box of 10 bottles of 25 doses / 50 ml glass bottle
- Box of 1 bottle of 50 doses / 100 ml LDPE bottle
- Box of 10 bottles of 50 doses / 100 ml LDPE bottle

Not all pack sizes may be marketed.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/054/001

8. DATE OF FIRST AUTHORISATION

06 June 2023

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22 December 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).