SUMMARY OF PRODUCT CHARACTERISTICS

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 (PRRS) virus, type 1, P120 strain .....≥ 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.

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White homogeneous emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (sows and gilts).

4.2 Indications for use, specifying the 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

4.3 Contraindications

None

4.4 Special warnings for each target species

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. Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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 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 product contains mineral oil. Even if small amounts have been injected, accidental injection with this 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.

Other precautions

Not applicable.

4.6 Adverse events

Porcine

Very common (>1 animal / 10 animals treated):	Elevated temperature [1] Injection site swelling [2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reaction 3

1 Increase in body temperature (average 1.3 °C, in individual pigs up to 2 °C) on the day of vaccination, which resolves within one day.

2 A local injection site swelling up to 5cm in diameter, lasting up to three days. These reactions do not need further treatment.

3 Immediate mild hypersensitivity-like reactions after vaccination, resulting in transient clinical signs such as vomiting.

4 Serious anaphylactic-type reactions (shock, recumbency) which may be fatal. Such reactions require prompt symptomatic treatment.

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Data are available which demonstrate that this vaccine can be administrated on a same day in a separate site, with inactivated vaccines against parvovirosis, 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.

4.9 Amount(s) to be administered and administration route

White homogeneous emulsion for injection.

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.

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

After administration of a double dose, no adverse reactions other than those described in section 4.6 were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae / Inactivated viral vaccines / porcine reproductive and respiratory syndrome (PRRS) virus.

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 IFA antibodies in vaccinated animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

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

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

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.

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

Medicines should not be disposed of via wastewater.
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

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER

Vm 14966/5079

9. DATE OF FIRST AUTHORISATION

21 September 2000

10. DATE OF REVISION OF THE TEXT

November 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall
Approved: 07 November 2025