[Version 9,11/2023] corr. 11/2023

ANNEX I

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 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.

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]

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

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

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

<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>
To be completed nationally

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

{Name}

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10, 20 or 50 ml glass bottle, 100 ml LDPE bottle
10 x 10 ml, 10 x 20 ml, 10 x 50 ml, 10 x 100 ml carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Progressis emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2-ml dose contains:
Inactivated porcine reproductive and respiratory syndrome (PRRS) virus, P120 strain ≥ 2.5 log 10 IF* units.
*IF units: ImmunoFluorescence antibody titre obtained after 2 injections in pigs under specific laboratory conditions.
O/w oily excipient (containing hydrogenated polyisobutene as adjuvant) ..... q.s. 1 dose of 2 ml.

3. PACKAGE SIZE

10-ml (5 doses)
20-ml (10 doses)
50-ml (25 doses)
100-ml (50 doses)
10 x 10-ml (5 doses)
10 x 20-ml (10 doses)
10 x 50-ml (25 doses)
10 x 100-ml (50 doses)

4. TARGET SPECIES

Pigs (sows and gilts).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10, 20 or 50 ml glass bottle, 100 ml LDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Progressis

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated porcine reproductive and respiratory syndrome (PRRS) virus, P120 strain ≥ 2.5 log 10 IF* units.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Progressis emulsion for injection

2. Composition

Each 2 ml dose contains:

Active substance:
Inactivated porcine reproductive and respiratory syndrome 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.

White homogeneous emulsion.

3. Target species

Pigs (sows and gilts).

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

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.

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.

Special precautions for the protection of the environment:
Not applicable.

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.

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

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.

Overdose:
After administration of a double dose, no adverse reactions other than those described in section 'Adverse events' were observed.

<Special restrictions for use and special conditions for use:>
<Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.>
To be completed nationally

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs (sows and gilts).

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[1]

Very rare	Injection site oedema (swelling)[2], Injection site granuloma[3]

[1]In such cases, an appropriate symptomatic treatment should be carried out.
[2]Oedema (at most 3 cm) lasting generally less than one week.
[3]Small 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system

{national system details}

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

Shake well before use.
Apply usual aseptic procedures.
The use of a multi-dosing syringe is recommended.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator.
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Email: pharmacovigilance@ceva.com
Phone number: +800 35 22 11 51

Manufacturer responsible for batch release:

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary

17. Other information

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.