LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 ml, 20 ml, 50 ml, 100 ml
10 x 10 ml, 10 x 20 ml, 10 x 50 ml, 10 x 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRESSIS emulsion for injection for pigs (sows and gilts)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2-ml dose of vaccine contains:
Inactivated Porcine Reproductive and Respiratory Syndrome (PRRS) virus, P120 strain $\geq$ 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. PHARMACEUTICAL FORM

Emulsion for injection

4. 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)

5. TARGET SPECIES

Pigs (sows and gilts).

6. INDICATION(S)

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 furrowing and the number of still-births.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular route
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – read package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 15052/4150

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml, 20 ml, 50 ml, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRESSIS emulsion for injection for pigs (sows and gilts)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml (5 doses);
20 ml (10 doses);
50 ml (25 doses)
100 ml (50 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP
Once opened use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

PROGRESSIS emulsion for injection for pigs (sows and gilts)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Manufacturer for the batch release:

BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE Laboratoire de Porte des Alpes, 99 rue de l'aviation, 69800 SAINT-PRIEST, France

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PROGRESSIS emulsion for injection for pigs (sows and gilts)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2-ml dose of vaccine contains:
Inactivated Porcine Reproductive and Respiratory Syndrome (PRRS) virus, P120 strain $\geq$ 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.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Vaccination may induce a transient oedema (at most 3 cm) lasting generally less than one week and 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. Vaccination may rarely cause hypersensitivity reactions. In such cases, an appropriate symptomatic treatment should be carried out.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (sows and gilts).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Do not freeze.
Shelf-life after first opening the container: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

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.

Special precautions for use in animals:
Vaccinate only healthy animals.
Apply usual procedures for the handling of animals

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

To the user:
This 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.

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 (symptoms, emergency procedures, antidotes):
After administration of a double dose, no adverse reactions other than those described in section "Adverse reactions" were observed.

Incompatibilities
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. 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 IFA antibodies in vaccinated animals.

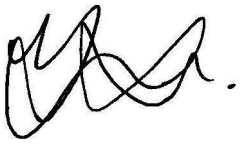
ATC Vet code: QI09AA05.

Pack sizes:
Cardboard box with 1 or 10 glass bottles of 10 ml (5 doses), 20 ml (10 doses) and 50 ml (25 doses).
Cardboard box with 1 or 10 LDPE bottles of 100 ml (50 doses).

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Representative of the marketing authorisation holder:



Approved: 12 October 2022