PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvovax

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 2ml dose contains:

Inactivated porcine parvovirus min 2.0HA1.U, Thiomersal: max 0.2mg, Benzyl alcohol: max 10.56mg.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1, 5 and 25 dose bottles in 1 bottle pakage

1 dose bottles in 10 bottle package

5. TARGET SPECIES

Breeder pigs

6. INDICATION(S)

For active immunisation of breeder pigs against porcine parvovirus, to reduce the number of stillbirths and mummified foetuses

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep intramuscular injection into the neck muscles.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

Accidental self –injection is dangerous.

Read package leaflet carefully before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store and transport between +2˚C and +8˚C, protected from light.

Use immediately after opening.

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

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14. THE WORDS "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

Vm 15052/4149

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvovax

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 2ml dose contains:

Inactivated porcine parvovirus min 2.0HA1.U, Thiomersal: max 0.2mg, Benzyl alcohol: max 10.56mg.

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

2ml = 1 dose

4. ROUTE(S) OF ADMINISTRATION

By deep i.m. injection into neck

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET FOR:

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 responsible for batch release:
BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE
Laboratoire Porte des Alpes – Rue de l'aviation, 69800 Saint-Priest – France
or
Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvovax

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

Each 2ml dose contains:

Inactivated porcine parvovirus min 2.0HA1.U, Thiomersal: max 0.2mg, Benzyl alcohol: max 10.56mg.

4. INDICATION(S)

For active immunisation of breeder pigs (gilts, sows, boars) against porcine parvovirus, to reduce the number of stillbirths and mummified foetuses in vaccinates. The onset of immunity is obtained from 2 to 3 weeks after primary vaccination. The immunity persists for up to one year.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Vaccination can induce a very small (<0.5cm) local reaction (granuloma) at the site of injection that disappears about one week later. Rarely vaccination may induce a slight rise in body temperature (around 1˚C) that returns to normal within 1-2 days. These effects are without consequence to the health or reproductive performance of the animal.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary practitioner.

7. TARGET SPECIES

Breeder pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

It is recommended to vaccinate all the breeders when implementing the vaccination programme.

Shake well before use.

Inject one 2ml dose by deep intramuscular injection into the neck muscles behind the ear, according to the following schedule:

Basic Vaccination scheme

Sows:

One dose only during lactation and at the latest on weaning day.

Gilts and young boars over 6 months of age:

In the absence of porcine parvovirus antibodies:

1 dose two weeks before service mating.

In the presence of maternally derived antibodies to porcine parvovirus or where the status is unknown as regards maternally derived antibodies:

2 doses with 15 or 21 day interval, the second dose being given at least 10 days before service mating.

Re-vaccination scheme:

Sows: Annual 2 ml dose preferably during lactation and prior to weaning.

Boars: annual 2 ml dose.

9. ADVICE ON CORRECT ADMINISTRATION

Apply usual procedures for the handling of animals.

Can be used during pregnancy and lactation.

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store and transport between +2˚C and +8˚C, protected from light.

Do not use after the expiry date stated on the label.

Use immediately after opening.

12. SPECIAL WARNING(S)

Vaccinate only healthy animals. Vaccinate sows during lactation.

No information is available on the safety or efficacy of the concurrent use of Parvovax with any other vaccine. It is therefore recommended that no other vaccine be administered within 14 days before or after vaccination with Parvovax.

Do not mix with any other product.

<User Warnings>

Apply aseptic procedures.

For Animal Treatment Only

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 insert 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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

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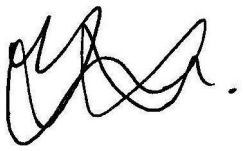

Approved: 06 October 2022