

[Version 8.2,01/2021]

B. PACKAGE LEAFLET

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very common adverse reactions:

Local redness can appear within 24 hours after the vaccination, which typically resolves without any treatment in less than 10 days but occasionally may persist up to 43 days.

Local temperature at the injection site can appear on the day of administration, which spontaneously resolves within 24 hours, although occasionally may persist up to 31 days.

Local pain at the injection site can appear on the day of administration, which typically resolves without any treatment before 4 days. Occasionally may persist up to 33 days.

Mild to moderate swelling (occasionally ≥ 5.1 cm) and nodules (≤ 5 cm) can appear on the day of vaccination at the injection site, which typically resolve without any treatment in less than 17 days but occasionally may persist up to 38 days (swelling) or 69 days (nodules).

A transient increase in body temperature (average 0.85 °C, maximum 2.45 °C) can appear within 6 hours after vaccination, which spontaneously resolves within 24 hours without any known consequence to the health or productivity of the animal.

These reactions were observed under experimental and field conditions.

Common adverse reactions:

Transient apathy can appear within 6 hours after vaccination, which resolved without treatment within 24 hours. This was observed under experimental and field conditions.

Hypersensitivity-like reactions, causing affected breathing and muscular stiffness, which resolved without treatment in a few minutes, was observed in one field study.

Uncommon adverse reactions:

General swelling in the neck can appear within two days after vaccination, which resolved without treatment within 13 days. This was observed under experimental and field conditions.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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.

Alternatively you can report via your national reporting system (national system detail).

7. TARGET SPECIES

Pigs.

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

Intramuscular use.

Administer one dose of 2 ml intramuscularly in the neck muscles to pigs from 12 weeks of age according to the following scheme:

Primary vaccination scheme: two intramuscular injections of one dose, 4 weeks apart.

Revaccination scheme: one intramuscular injection of one dose at least every 5 months.

Can be used for vaccination of pregnant animals, however if vaccinating according to the primary vaccination scheme, administer the first dose prior to mating or insemination.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use and intermittently during the process of vaccination.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

Keep the vial in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after EXP. The expiry date refers to the last date of that month.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

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 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 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.

People with known hypersensitivity to thiomersal should avoid contact with the product.

Pregnancy and lactation:

Can be used during pregnancy and lactation, in accordance with the recommendations in Dosage Section.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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):

No information is available in the administration of an overdose of this vaccine.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[For MRP/DCP: To be completed in accordance with national requirements after conclusion of the MR phase.]

15. OTHER INFORMATION

Pack size:

Cardboard box with 1 vial containing 100 ml.

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