COXEVAC®

Product information

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These pages are general information pages. No guarantee is given as to the completeness of the information contained or its compliance with national regulatory requirements. Users should consult the local site of their countries to obtain information that complies with applicable national regulations.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COXEVAC suspension for injection for cattle, goats and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Inactivated *Coxiella burnetii*, strain Nine Mile ..... ≥ 72 QF Units*

*QF (Q fever) Unit: relative potency of phase I antigen measured by ELISA in comparison with a reference item.

Excipient:

Thiomersal ..... ≤ 120 µg

Sodium chloride

Disodium hydrogen phosphate

Potassium dihydrogen phosphate

Water for injections (QS 1 ml)

3. PHARMACEUTICAL FORM

Suspension for injection.

Whitish, opalescent, homogeneous suspension.

4. CLINICAL INFORMATION

4.1 | Target species

Cattle, goats and sheep

4.2 | Indications for use for each target species

Cattle:

For the active immunisation of cattle to lower the risk for non-infected animals vaccinated when non-pregnant to become shedder (5 times lower probability in comparison with animals receiving a placebo), and to reduce shedding of *Coxiella burnetii* in these animals via milk and vaginal mucus.
Onset of immunity: not established.
Duration of immunity: 280 days after completion of the primary vaccination course.

Goats:

For the active immunisation of goats to reduce abortion caused by *Coxiella burnetii* and to reduce shedding of the organism via milk, vaginal mucus, faeces and placenta.
Onset of immunity: not established.
Duration of immunity: one year after completion of the primary vaccination course.

Sheep:
For the active immunisation of sheep against *Coxiella burnetii*, to reduce shedding of the organism via milk, vaginal mucus and faeces.
Onset of immunity: not established
Duration of immunity: 4 months

4.3 | Contraindications

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).

4.4 | Special warnings for each target species

Vaccinate healthy animals only.

Vaccination of animals already infected at the time of vaccination will have no adverse reaction.

No efficacy data are available concerning the use of COXEVAC in male animals. However, in safety laboratory trials, the use of COXEVAC in males proved to be safe. In the case that it is decided to vaccinate the whole herd, it is advisable to vaccinate the male animals at the same time.

There are no benefits of the vaccine (as described in the indications for cattle), when used in infected and/or pregnant cows.

The biological significance of the levels of reduction shown in shedding in cattle and goats is not known.

4.5 | Special precautions for use

Special precautions for use in the target species

It is advisable to vaccinate all the animals in the herd at the same time.

Under field conditions, vaccination with COXEVAC has commonly been followed by a decrease in milk production in goats. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment

Not applicable.

Other precautions

None.

4.6 | Adverse events

Cattle:
Very common (>1 animal / 10 animals treated): injection site swelling (palpable, of 9 to

10 cm diameter maximum, which may last for 17 days, reduces gradually and disappears without need for treatment).
Rare (1 to 10 animals / 10,000 animals treated): lethargy; hyperthermia; anorexia.

Goats:
Very common (>1 animal / 10 animals treated): injection site swelling (palpable, of 3 to 4 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment); hyperthermia (for 4 days post-vaccination).
Uncommon (1 to 10 animals / 1,000 animals treated): lethargy; malaise; anorexia.
Rare (1 to 10 animals / 10,000 animals treated): diarrhoea.

Sheep:
Very common (>1 animal / 10 animals treated): Injection site inflammation, application site thickening (palpable, of 5 cm diameter maximum, which may last for 14 days, reduces and disappears without need for treatment. Reactions are expected to be more severe after the second injection).
Rare (1 to 10 animals / 10,000 animals treated): lethargy; hyperthermia; anorexia.

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 the national competent authority via the national reporting system. See also section "Contact details" of the package leaflet.

4.7 | Use during pregnancy, lactation or lay

Pregnancy and lactation:

Cattle and goats:
The safety of the veterinary medicinal product has not been established during pregnancy. The vaccine can be used during lactation.
Under field conditions, vaccination with COXEVAC has been followed by a decrease in milk production, commonly in goats and rarely in cattle. Since stress could contribute to this adverse reaction, appropriate precautions should be taken to reduce stress as much as possible during the administration of the product.

Sheep:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

4.8 | 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.

4.9 | Amounts to be administered and administration route

Subcutaneous use.
Shake well before use.

Administer the vaccine as follows:

Cattle: 4 ml in the neck region.
Goats: 2 ml in the neck region.
Sheep: 2 ml in the neck region.

Cattle from 3 months of age:

Primary vaccination:
Two doses should be given subcutaneously with an interval of 3 weeks. Under normal conditions the timing of vaccination should be planned so that the primary course is completed by 3 weeks before artificial insemination or mating.

Re-vaccination:
Every 9 months, as described for primary vaccination, based on duration of immunity of 280 days.

Goats from 3 months of age:

Primary vaccination:
Two doses should be given subcutaneously with an interval of 3 weeks. Under normal conditions the timing of vaccination should be planned so that the primary course is completed by 3 weeks before artificial insemination or mating.

Re-vaccination:
One dose should be given yearly.

Sheep from 4 months of age:

Primary vaccination:
Two doses should be given subcutaneously with an interval of 3 weeks. The vaccination should be done as late as possible, but the primary course needs to be completed by 3 weeks before artificial insemination or mating.

Re-vaccination:
Prior to each artificial insemination or mating, two doses, 3 weeks apart; the vaccination course should be done as late as possible but needs to be completed at least 3 weeks before the intended start of the reproduction phase.

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

Cattle:
With double dose, a palpable reaction of maximum diameter of 10 cm was observed at the injection site, lasting for 16 days. The reaction gradually reduced and disappeared without need for treatment.

Goats:
With double dose, a moderate palpable reaction of diameter of 4 to 5 cm was observed at the injection site, lasting for 4 days. The reaction reduced and disappeared without need for treatment.

Sheep:
With double dose, a moderate palpable reaction of diameter of less than 2 cm was

observed at the injection site, lasting for 12 days. The reaction reduced and disappeared without need for treatment.

4.11 | Withdrawal period(s)

Meat, milk and offal: Zero days.

5. IMMUNOLOGICAL INFORMATION

ATCvet code: QI02AB.

The vaccine contains phase I *Coxiella burnetii* as active ingredient inducing active immunity against Q fever in cattle and goats.

6. PHARMACEUTICAL PARTICULARS

6.1 | Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.2 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.3 | Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.4 | Nature and composition of immediate packaging

Carton box with 1 plastic (LDPE) bottle, containing 40 ml of suspension.
Carton box with 1 plastic (LDPE) bottle, containing 100 ml of suspension.
Each container is closed with a 20 mm bromobutyl rubber stopper and a central tear-off aluminium-plastic cap.

Not all pack sizes may be marketed.

6.5 | 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 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 national collection systems applicable to the veterinary medicinal product concerned.