SUISENG Diff/A

Suspension for injection for pigs

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT:
Marketing authorisation holder and manufacturer responsible for batch release:
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NAME OF THE VETERINARY MEDICINAL PRODUCT:
Suiseng Diff/A suspension for injection for pigs.

STATEMENT OF THE ACTIVE SUBSTANCE(S):
Each dose (2 ml) contains:
Active substances:

Clostridioides difficile, toxoid A (TcdA)	≥ 1.60 RP*
Clostridioides difficile, toxoid B (TcdB)	≥ 1.65 RP*
Clostridium perfringens type A, α-toxoid	≥ 1.34 RP*

*RP: Relative Potency determined by ELISA

Yelllowish-white suspension.

INDICATION(S):
For the passive immunisation of neonatal piglets by means of the active immunisation of breeding sows and gilts:
- To prevent mortality and reduce clinical signs and macroscopic lesions caused by *C. difficile*, toxins A and B.
- To reduce clinical signs and macroscopic lesions caused by *C. perfringens* type A, α-toxin.

The reduction of the occurrence of neonatal diarrhoea has been demonstrated under field conditions.
Onset of immunity:
Protection was demonstrated in suckling piglets on the first day of life in challenge studies.
Duration of immunity:
Neutralising protective antibodies transferred via colostrum to the piglets were present up to 28 days after birth in the majority of the piglets.

CONTRAINDICATIONS:
Do not use in cases of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

ADVERSE REACTIONS:
Mild local inflammation at the injection site (maximum diameter of 5 cm) which subsided without treatment within 5 days was commonly reported in laboratory studies.
A slight transient increase in body temperature (mean 0.27 ºC, in individual pigs up to 0.95 ºC) which subsided without treatment occurred commonly in preclinical and field studies.
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.

TARGET SPECIES:
Pigs (pregnant sows and gilts).

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION:
Administer the vaccine by deep intramuscular injection in the neck muscles.
Dose: 2 ml/animal.
Primary vaccination:
Administer one dose (2 ml) at approximately 6 weeks before farrowing and a second dose (2 ml) at approximately 3 weeks before farrowing.
It is recommended that the second dose is given preferably on alternate sides.
Revaccination:
On each subsequent gestation, administer one dose (2 ml) 3 weeks before the expected date of farrowing.

ADVICE ON CORRECT ADMINISTRATION:
Allow the vaccine to reach room temperature (15 ºC to 25 ºC) before use. Shake well before use.

WITHDRAWAL PERIOD(S):
Zero days.

SPECIAL STORAGE PRECAUTIONS:
Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC-8 ºC). Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the container: 10 hours.

SPECIAL WARNING(S):
Special warnings for each target species
Vaccinate healthy animals only.
Protection of piglets is achieved by colostrum intake. Therefore, care should be taken to ensure that each piglet ingests a sufficient quantity of colostrum within the first hours of life.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
None.
Pregnancy and lactation
Can be used during pregnancy.
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)
None known.
Incompatibilities
Do not mix with any other veterinary medicinal product.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:
November 2021
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

OTHER INFORMATION:
20 ml, 50 ml, 100 ml and 250 ml PET bottles, closed with bromobutyl-stoppers and aluminium caps.
Pack sizes:
Cardboard box with 1 PET bottle of 10 doses (20 ml bottle).
Cardboard box with 1 PET bottle of 10 doses (50 ml bottle).
Cardboard box with 1 PET bottle of 25 doses (50 ml bottle).
Cardboard box with 1 PET bottle of 25 doses (100 ml bottle).
Cardboard box with 1 PET bottle of 50 doses (100 ml bottle).
Cardboard box with 1 PET bottle of 50 doses (250 ml bottle).
Not all pack sizes may be marketed.

The active immunisation of pregnant sows and gilts induces the production of neutralising antibodies against *C. difficile*, toxins A and B and *C. perfringens* type A, α-toxin. These antibodies are transferred via the colostrum to the piglets. The uptake of sufficient colostrum within the first hours of life results in a passive protection of piglets. Efficacy of the vaccine was demonstrated upon intraperitoneal challenge with *C. difficile* toxin A and B and alpha toxin from *C. perfringens* type A. The efficacy of the vaccine to reduce the occurrence of diarrhoea was demonstrated under field conditions.

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

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