SUISENG® Coli/C

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:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 - AMER (Girona) SPAIN
Tel. +34 972 430660
Fax. +34 972 430661
E-mail: hipra@hipra.com

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S):

Each dose (2 ml) contains:

F4ab fimbrial adhesin of *E. coli*	≥ 65% ER_{60} *
F4ac fimbrial adhesin of *E. coli*	≥ 78% ER_{70}
F5 fimbrial adhesin of *E. coli*	≥ 79% ER_{50}
F6 fimbrial adhesin of *E. coli*	≥ 80% ER_{25}
LT Enterotoxoid of *E. coli*	≥ 55% ER_{70}
Toxoid *Clostridium perfringens*, type C	≥ 35% ER_{25}
Toxoid *Clostridium novyi*, type B	≥ 50% ER_{120}

*% ERx: Percentage of immunized rabbits with a x serological EIA response.

White-yellowish suspension.

INDICATION(S):

Piglets: For the passive protection of neonatal piglets by means of the active immunisation of breeding sows and gilts to reduce mortality and clinical signs of neonatal enterotoxicosis, such as diarrhoea caused by enterotoxigenic *Escherichia coli*, which express F4ab (K88ab), F4ac (K88ac), F5 (K99) or F6 (987P) adhesins.
The persistence of these antibodies has not been established.
For the passive immunisation of neonatal piglets against Necrotic Enteritis by means of the active immunisation of breeding sows and gilts to induce seroneutralising antibodies against the β-toxin of *Clostridium perfringens* type C.
The persistence of antibodies has not been established.
Sows and gilts: For active immunisation of breeding sows and gilts to induce seroneutralising antibodies against α-toxin of *Clostridium novyi* type B. The relevance of the seroneutralising antibodies was not experimentally determined.
Antibodies have been detected 3 weeks after the completion of the basic vaccination scheme. The persistence of these antibodies has not been established.

CONTRAINDICATIONS:

None.

ADVERSE REACTIONS:

Very rare adverse reactions:
- A small granuloma may occur in the muscle tissue at the injection site. The administration of the vaccine can cause the appearance of a small (less than 3 cm), local, transitory swelling (for 24-48 hours). In a few cases, temporary small nodules can be observed, which disappear within 2-3 weeks.
- The vaccination may cause a slight increase in body temperature for a transient period after vaccination (4-6 hours after injection).Unusually, an increase in rectal temperature higher than 1.5ºC, lasting less than 6 hours, may occur.

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 www.hpra.ie for IE and https://www.gov.uk/report-veterinary-medicine-problem for UK.

TARGET SPECIES:

Pigs (sows and gilts).

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

Intramuscular, into the neck muscles. Dose: 2 ml/animal.
The basic vaccination scheme consists of two doses: the first dose at approximately 6 weeks before farrowing and a second dose at approximately 3 weeks before farrowing. It is recommended that the second dose should be given preferably on alternate sides Revaccination: On each subsequent gestation, administer one dose 3 weeks before the expected date of farrowing.

ADVICE ON CORRECT ADMINISTRATION:

It is advisable to administer the vaccine at a temperature between +15ºC and +25ºC. Shake before use.

WITHDRAWAL PERIOD(S):

Zero days.

SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.
Store and transport refrigerated (2ºC - 8ºC). Protect from light. Do not freeze.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 10 hours.

SPECIAL WARNING(S):

Special precautions for use in animals: Vaccinate healthy animals only. Hypersensitivity reactions may occur in sensitive animals. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.
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.
Pregnancy and lactation: Can be used during pregnancy from 6 weeks before the expected farrowing date.
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), if necessary: No effects other than those indicated under section "Adverse reactions" have been observed following the administration of a double dose.
Incompatibilities: Do not mix with any other veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon 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: 02/04/2020

OTHER INFORMATION: Pack sizes:
- Cardboard box with 1 glass or PET vial of 10 doses (20 ml).
- Cardboard box with 1 glass or PET vial of 25 doses (50 ml).
- Cardboard box with 1 glass or PET vial of 50 doses (100 ml).
- Cardboard box with 1 PET vial of 125 doses (250 ml).

Not all pack sizes may be marketed.
IE only: Licensed Merchant. Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary practitioner is sought.
FOR ANIMAL TREATMENT ONLY

UK only:
POM-V Prescription Only Medicine
Vm: 17533/4020
To be supplied only on veterinary prescription

IE only:
LM Licensed Merchant
VPA 10846/019/001.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
Local Representative: HIPRA UK AND IRELAND, Ltd.
Tel: (+44) 0115 845 6486

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135 . 17170 Amer (Girona) SPAIN
Tel. (34) 972 43 06 60. Fax (34) 972 43 06 61. hipra@hipra.com