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Salmoporc, lyophilisate and solvent for suspension for injection for pigs

Authorised

 Salmonella enterica, subsp. enterica, serovar Typhimurium, strain 421/125 (histidine-adenine auxotrohic), Live

Product identification

Medicine name:

Salmoporc, liofilizado e solvente para suspensão injetável para suínos Salmoporc, lyophilisate and solvent for suspension for injection for pigs

Active substance:

Salmonella enterica, subsp. enterica, serovar Typhimurium, strain 421/125 (histidine-adenine auxotrohic), Live

Target species:

Pig

Route of administration:

Oral use

Subcutaneous use

Product details

Active substance and strength:

Salmonella enterica, subsp. enterica, serovar Typhimurium, strain 421/125 (histidineadenine auxotrohic). Live

8.00 log10 colony forming unit(s) / 1.00 millilitre(s)

Pharmaceutical form:

Lyophilisate for suspension for injection

Withdrawal period by route of administration:

Oral use:

Pig

- Meat and offal. 6 week six weeks after the second vaccination

Subcutaneous use:

Piq

- Meat and offal. 6 week six weeks after the second vaccination

Anatomical therapeutic chemical veterinary (ATCvet) codes:

OI09AE02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Portugal

Package description:

Cardboard box containing 1 vial with 20 doses (1 dose = 1 ml) lyophilised vaccine 1 vial with 20 ml solvent

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Similar biological application (Article 13(4) of Directive No 2001/82/EC)

Marketing authorisation holder:

Ceva Saude Animal Produtos Farmaceuticos E Imunologicos Lda.

Marketing authorisation date:

21/02/2019

Manufacturing sites for batch release:

Ceva-Phylaxia Co. Ltd IDT Biologika GmbH

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

966/01/19DIVPT

Date of authorisation status change:

4/11/2022

Reference member state:

Netherlands

Procedure number:

NL/V/0247/001

Concerned member states:

Austria Belgium Czechia Denmark Hungary Ireland Italy Portugal Romania Slovakia United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet