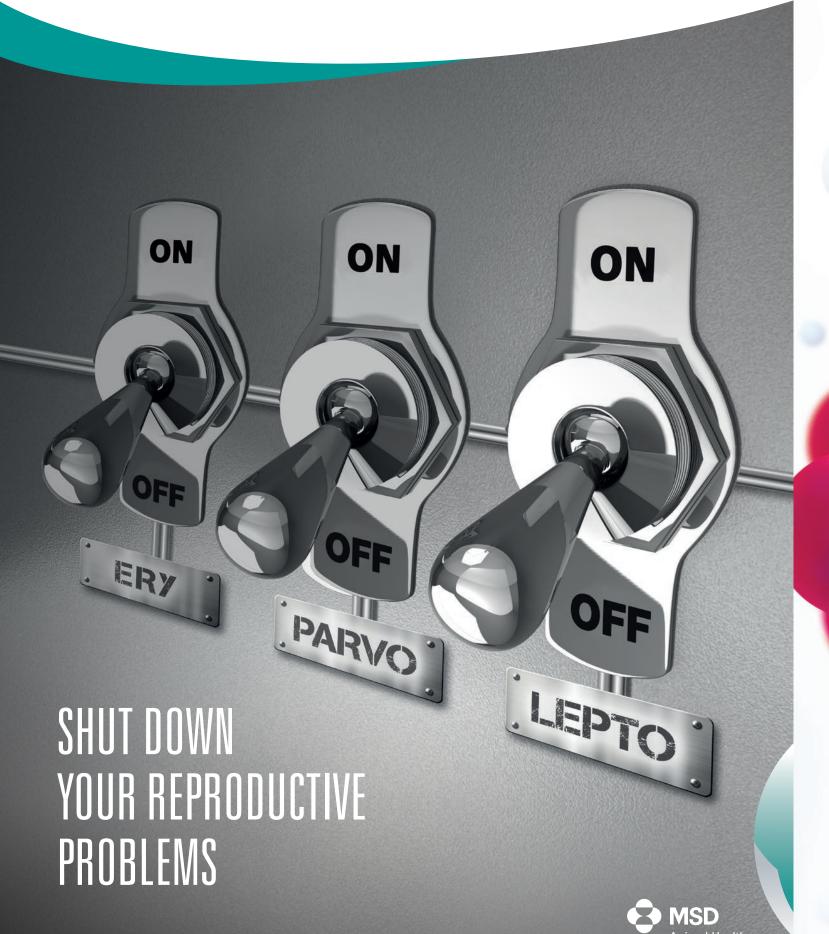


The efficacy of a triple protection



ERISIPELAS, PARVOVIRUS and LEPTOSPIRA **WHY DO THEY MATTER?**

Swine erysipelas, parvovirus and *Leptospira* are economically important pathogens, whose presence in the herd has negative impact on sows and gilts reproductive performances world-wide.

Impact on reproductive performances:

- Irregular returns to oestrus
- Small litters
- Abortion, mummified fetuses, neonatal death
- Infertility & failure to farrow

ERYSIPELAS

(Erysipelothrix rhusiopathiae)

• Piglet sudden death Abortion

Other clinical signs:

- High fever (41 to 42 °C)
- Inappetence: dry faeces
- Diamond-like skin lesions
- Septicaemia
- Chronic disease: Arthritis, Endocarditis

Impact on reproductive performances:

- Abortions
- Stillbirths
- Return to oestrus during first weeks of pregnancy

THE PATHOGENS

PARVOVIROSIS (Porcine Parvovii

OFF

Impact on reproductive performances:

Pain in the legs: stilted, stiff movement, arched back line

LEPTOSPIROSIS (9 serovars)

PORCILIS[®] ERY + PARVO + LEPTO THE TRIPLE PROTECTION **IN 1 PRODUCT**

Porcilis[®] Ery+Parvo+Lepto is the only vaccine in the market containing erysipelas, parvovirus, and the three main *Leptospira* serogroups known for causing reproductive failures in the field (Australis, Pomona and Tarassovi)*.

Porcilis[®] Ery+Parvo+Lepto also contains *Leptospira* serogroups Canicola, Icterohaemorrhagiae and Grippotyphosa.

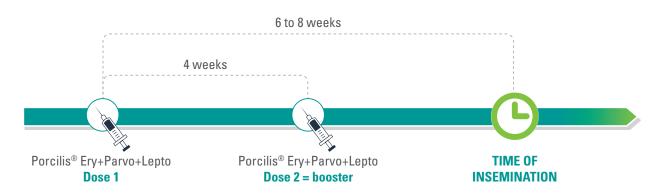
DID YOU KNOW?

OFF

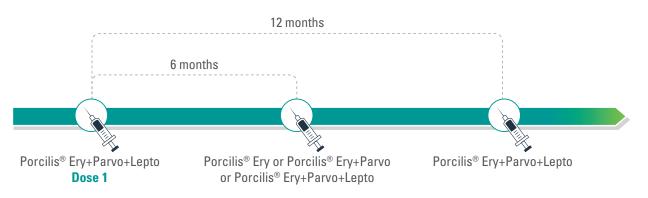
THE PROGRAM

Porcilis[®] Erv+Parvo+Lepto can be used in **mass vaccination** without any risk for the pregnant animals or their progeny

Vaccination program **First vaccination/gilts**



Revaccination



* see SPC for full information on indication for use and claims per antigen and serovar. In case of expected L. interrogans serogroup Australis problems, a single revaccination with Porcilis® Ery + Parvo + Lepto should be given every six months.

1 - Jacobs, A.A.C., et al. (2015). A novel octavalent combined erysipelas, parvo and Leptospira vaccine provides (cross) protection against infection following challenge of pigs with 9 different Leptospira interrogans serovars. Porcine Health Management 1:16 pp 1-7. 2&3&4 - Jacobs, A.A.C., et al. (2015). Safety and efficacy of a new octavalent combined erysipelas, parvo and Leptospira vaccine in gilts against L. interrogans serovar Pomona associated disease and foetal death. Vaccine 33 pp 3963-3969. 5 - Data on file.

Indications for use: For the active immunization of pigs: to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by Ervsipelothrix rhusiopathiae, serotype 1 and serotype 2. To reduce transplacental infection, viral load and foetal mortality caused by Porcine parvovirus. To reduce clinical signs (increase of body temperature and reduction in feed intake or activity), infection and bacterial excretion caused by L. interrogans serogroup Canicola serovar Canicola. To reduce clinical signs (increase of body temperature and reduction in feed intake or activity), severity of infection and foetal mortality caused by L. interrogans serogroup Pomona serovar Pomona. To reduce infection caused by L. interrogans serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, L. interrogans serogroup Australis serovar Bratislava, L. kirschneri serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, L. weilii serogroup Tarassovi serovar Vughia and L. borgpetersenii serogroup Tarassovi serovar Tarassovi. Onset of immunity: E. rhusiopathiae: 3 weeks; Porcine parvovirus: 10 weeks; Leptospira serogroups: 2 weeks. Duration of immunity: E. rhusiopathiae: 6 months; Porcine parvovirus: 12 months; Leptospira serogroup Australis: 6 months; Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 12 months. Administration: For intramuscular use. Administer a single dose of 2 ml in the neck region. Vaccination scheme: Basic vaccination: Pigs which have not yet been vaccinated shall be given a primary injection 6 to 8 weeks before the expected date of insemination and a booster injection 4 weeks later. Revaccination: A single revaccination with the veterinary medicinal product should be given once a year. Six months post each vaccination with the veterinary medicinal product, a single revaccination with an Erysipelotrix rhusiopathiae containing product should be given to maintain immunity against Erysipelotrix rhusiopathiae. In case of known infection pressure with L. interrogans serogroup Australis, a single revaccination with the veterinary medicinal product should be given every six months, as it is unknown if or for how long the duration of immunity for this serogroup persists beyond six months. Adverse reactions: An increase in body temperature may very commonly occur up until two days after vaccination. The observed mean increase was 0.5°C (in individual cases the maximum increase was 1.5°C). Transient local reactions, mostly consisting of red, mild to hard, non-painful swellings are a very common observation. In general, local reactions may have a diameter of \leq 5 cm, in very rare cases local reactions in individual animals can be up to 20 cm in diameter. All local reactions disappear completely within approximately 2 weeks after vaccination. In individual animals intermediate systemic reactions, such as vomiting, redness, rapid breathing and twitching, may rarely be observed, which resolve in a few minutes. In individual animals transient reductions in feed intake or activity may uncommonly occur. Feed intake and activity are completely restored within a week.



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PORCILIS[®] ERY+PARVO+LEPTO **THE BROADEST PROTECTION** AGAINST LEPTOSPIRA¹

No other vaccine in the market offers protection against 9 different serovars of *Leptospira*.

Protection		Porcilis®		Vaccine C
Leptospira		Ery + Parvo + Lepto (MSD AH)	Vaccine A + B	
Serogroups	Serovars			
Pomona	Pomona	er e	ar ar	B CON
Canicola	Canicola	T T	are.	and the second se
lotorohoomorrhogioo	lcterohaemorrhagiae	T T	are a second sec	a contraction of the second seco
lcterohaemorrhagiae	Copenhageni	ar and a second s		
Australis	Bratislava	W	and a second sec	
Grinnotunhoco	Grippotyphosa	T T	are a second sec	a contraction of the second seco
Grippotyphosa	Bananal	W		
Tarassovi	Tarassovi	a construction of the second sec		
	Vughia	V		
Sejroe	Hardjo		ar ar	a Co
Total serovars		9	6	5

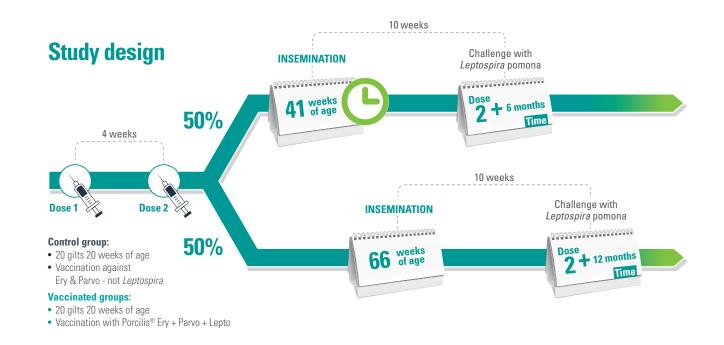
THE PROTECTION

OFF



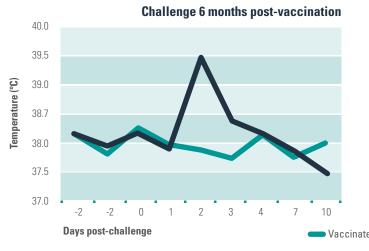
THE BEST PROTECTION AGAINST FOETAL DEATH FOR AT LEAST ONE YEAR²

Porcilis[®] Ery+Parvo+Lepto is the only vaccine in the market with proven efficacy on reducing foetal mortality caused by Parvovirus and *Leptospira* serovar *Pomona*.



Study	results
ouu	ioouno

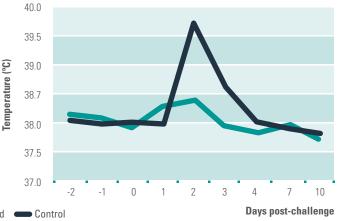
Study results Increase of serum titres after challenge		Control	Vaccinated with Porcilis® Ery+Parvo+Lepto	Statistically significant
		++	+	YES
Foetal deaths, autolysis and/or mummies (% of total litter size)	Challenge at 6 months post vaccination	21 %	3%	P=0.0003
	Challenge at 12 months post vaccination	27 %	2%	P=0.0076



LA3 EFFICACY

Challenge 12 months post-vaccination

OFF



THE LONGEST COMBINED PROTECTION

FOR THE THREE PATHOGENS

	DOI
Erysipelas	6 months
Parvovirus	12 months
L. Pomona	12 months
L. Canicola	12 months
L. Icterohaemorrhagiae	12 months
L. Australis	6 months
L. Grippotyphosa	12 months
L. Tarassovi	12 months
	12 montuis

SAFETY



PORCILIS[®] ERY+PARVO+LEPTO A VERY SAFE VACCINE³

Safety study 1

Design

- 12 gilts (16 weeks of age). Vaccinated with 2 ml of Porcilis[®] Ery+Parvo+Lepto in neck.
- Necropsied 2 weeks later.

Results^{*}

Temperature: No vaccine-related rectal temperature increase or other systemic related reactions.

Safety study 2

Design

- 14 gilts (16 weeks of age). Vaccinated with a PRRS vaccine + 4 ml (double dose) of Porcilis[®] Ery+Parvo+Lepto.
- Concomitant in neck.
- Revaccination with 1 dose of both vaccines 2 weeks after.
- Pigs were observed daily for local and systemic reactions during 14 days after each vaccination. Rectal temperature was determined on day 1, 2 and 3 before each vaccination, just before vaccination, 4 h after vaccination and then once daily for four days after each vaccination.

* The safety of the product has been studied extensively. Please find the complete overview of adverse reactions as indicated on the SPC on the last page of the brochure.

Results*

Site/local reactions: No local reactions following vaccination, except one gilt (on 36) with a small local reaction for 5 days after the third vaccination.

THE ONLY LEPTO VACCINE WITH FIELD EFFICACY STUDIES⁴

Study set up

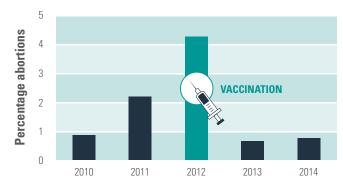
• Field study based on historical comparison of farm performances in Portugal.

Treatment

- 2 vaccinations with Porcilis[®] Ery+Parvo+Lepto.
- 4 week-interval.
- **Revaccination:** second week of every following lactation.

Study results

Demonstrate vaccination effect on incidence of abortions (results of study compared to historical data).



	Pre-vaccination	Post-vaccination
	2011: 12/2010 - 11/2011: 2.3%	2013: 12/2012 - 03/2013: 0.5% (-96%
Abortions	2012: 12/2011 - 11/2012: 4.4% 12/2011 - 03/2012: 12.6%	TOTAL OF 6 ABORTIONS IN 2013 (-89%) VERSUS FULL YEAR 2012
	TOTAL OF 55 ABORTIONS IN 2012	2014: 12/2013-04/2014: 0.6%



FIELD EFFICACY



OFF

THE VACCINE THAT CAN BE USED **DURING PREGNANCY⁵**

Study design

Crown	# of gilts We		Porcilis	o+Lepto	
Group	IM injection in neck	gestation	TO	+2 weeks	+4 weeks
I	9	3 to 7	Double	Single	Single
Ш	12	9 to 12	Double	Single	Single

Study results

Group	Gestation	Average duration of gestation (days)	Average piglets per gilt		
			Total	Alive	Dead
I	Early	114.8	10.3	7.6	2.8
II	Late	114.1	14.1	12.6	1.5

Vaccination of gilts with Porcilis® Ery+Parvo+Lepto did not induce abortion or congenital abnormalities or any other vaccine related problems with the offspring. Porcilis[®] Ery+Parvo+Lepto vaccine is safe for pregnant pigs*.

*All piglets were normally developed. The causes of death were not related to the vaccine, but to long lasting complicated partus, trauma, diarrhoea, bacterial sepsis or due to weak piglets as a result of large litters. The average numbers of piglets in the two groups were different. This was not unexpected as the gilts in the two groups were not at the same age at partus which might have an influence on the number of piglets. Moreover, since the two groups were not inseminated at the same time, the insemination technique and its success cannot be expected to be identical. The two groups can therefore not be directly compared to each other for the number of piglets.