STARTVAC® 3

Inactivated vaccine against *E.coli. S. aureus* and CNS

Results of field trials approved by the European Medicines Agency (EMEA):

1. Principal aims and results

	Variable	STARTVAC® Group	PLACEBO Group	Statistical significant differences between STARTVAC ® and PLACEBO (α = 0.05)
Percentage of clinical and subclinical mastitis until 130 days	*S. aureus*	118%	10.34%	0.001
	E. coli	4.14%	17.82%	0.001
	CNS	16.57%	32.18%	0.001
Percentage of clinical mastitis until 130 days	*S. aureus*	0.00%	2.87%	0.032
	E. coli	1.78%	6.90%	0.02
	CNS	2.37%	6.90%	0.047
Percentage of subclinical mastitis until 130 days	S .*aureus*	1.18%	9.77%	0.001
	E. coli	2.37%	13.22%	0.001
	CNS	15.98%	39.89%	0.002
Spontaneous cure rate	Multiparous	44.19%	20.45%	< 0.05
	Primiparous	53.33%	50.00%	> 0.05
	Total	51.43%	32.18%	< 0.05

2. Secondary aims and results

Variable	STARTVAC® group	PLACEBO group	Statistical significant differences between STARTVAC® and PLACEBO (α = 0.05)	Observations
Somatic cell count (mean SSC x 10^3)	328.2	548.6	SI (p<0.05)	Internationally recognized indicator for mastitis and milk quality
Milk aspect (>1)	11.42 %	19.79 %	SI (p<0.05)	Implies less economic losses due to lost quarters, discarded milk and replacement cows
Mammary gland aspect (>1)	14.44 %	24.03%	SI (p<0.05)	
Treatment with pharmacological products	34 treat.	93 treat.	SI (p<0.05)	Implies less economic losses due to treatments and reduces the risk of residues in milk
	22 cows	40 cows		
Death of cows due to mastitis	0	3	NO (p>0.05)	Low number of deaths, Death due to mastitis only occurred in the placebo group

HIPRA

COMPOSITION PER DOSE (2 ML): Inactivated *Escherichia coli* (J5) > 50 RED_{60}*; Inactivated *Staphylococcus aureus* (CP8) SP 140 strain expressing SAAC** > 50 RED_{80}***. Adjuvant. * RED_{60}: Rabbit effective dose in 60% of the animals (serology). **SAAC: Slime Associated Antigenic Complex. ***RED80: Rabbit effective dose in 80% of the animals (serology). **INDICATIONS:** Cows and Heifers: To prevent Mastitis. For herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by Staphylococcus aureus, coliforms and coagulase-negative staphylococci. The full immunisation scheme induces immunity from approximately day 13 after the first injection until approximately day 78 after the third injection (equivalent to 130 days post-parturition). **SIDE EFFECTS:** Slight to moderate transient local reactions may occur after the administration of the vaccine, which disappears within 1 or 2 weeks at most. **ADMINISTRATION ROUTE:** Intramuscular, into the neck muscles. The injections should be preferably administered on the alternate sides of the neck. It is advisable to administer the vaccine at a temperature between +15 and +25 ºC. Shake before use. **DOSAGE:** Cows and Heifers: 2 ml/animal. Generally, the following vaccination programme is recommended: First injection: at 45 days before the expected parturition date. Second injection: 35 days thereafter (corresponding to 10 days before the expected parturition date). Third injection: 62 days after the second injection (equivalent to 52 days post-parturition). The full immunisation programme should be repeated with each gestation. The whole herd should be immunised. Immunisation has to be considered as one component in a complex mastitis control program that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, bedding, cow confort, air and water quality, health monitoring) and other management practices. It can be used during pregnancy and lactation. **WITHDRAWAL PERIOD:** 0 days. **SPECIAL PRECAUTIONS:** Store at +2 to +8 ºC, avoiding freezing. Protect from light. **PACKAGING:** Pack of 20 vials of 1 ds. (**EU**/2/08/092/003) / 5 ds vial. (**EU**/2/08/092/004) 25 ds bottle. (**EU**/2/08/092/006). Under veterinary prescription.