VMD incidence figures for injection site sarcomas in cats reported as adverse reactions after vaccination

IMPORTANT NOTES

The information provided below is for guidance only and should be interpreted with caution. Vaccines for which injection site sarcomas have not been reported to the VMD as adverse reactions following their administration and those with total sales volumes of less than 100,000 doses are not included.

The VMD has agreed with industry to provide adverse reaction incidence figures in response to enquiries about the numbers of adverse reactions reported in a given period. This enables the VMD to provide information about adverse reaction incidence in the context of sales volumes without disclosing commercially sensitive details.

The VMD incidence figures for injection site sarcomas are derived from UK data in periodic safety update reports for the individual vaccines provided by the respective marketing authorisation (MA) holders at intervals specified in legislation since the MAs were first issued. Due to the various dates on which the MAs were issued, the figures are for differing periods and may not reflect the situation immediately preceding the current date. The sales data on which the figures are based are not subject to independent verification and the VMD does not guarantee their accuracy.

The number of doses refers to the number of individual doses of vaccine which have been sold and not to recommended vaccination schedules.

The VMD incidence figures include adverse reactions resulting from off-label use, i.e. accidental misuse or use not in accordance with the manufacturer's instructions.

Other products or implants such as identification chips may have been administered either topically or subcutaneously at the same site at the same time as vaccination, or at the same site at different times. The VMD incidence figures are based on products identified as the suspect products by the reporters of the adverse reactions.

'Injection site sarcoma' is the term used in veterinary pharmacovigilance to describe a tumour which develops at an injection site. It is a generic term covering all such tumours, even if they have been more precisely characterised as fibrosarcomas, myofibrosarcomas, etc. by viewing their tissue cells under a microscope. The term is listed in the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA), which is the internationally recognised dictionary of clinical signs mentioned in veterinary pharmacovigilance legislation.

The table provided below is the property of the VMD and must not be copied, published or otherwise reproduced without the permission of the VMD.

Product Name	MA Holder	MA Number	Incidence Rate (%)	Incidence Explanation	Start Date	End Date
Eurifel P*	Merial	08327/4008	0.00035	0.4 per 100,000 doses	15/04/1988	31/12/2001
Eurifel RC*	Merial	08327/4007	0.00004	0.04 per 100,000 doses	06/06/1988	31/12/2000
Eurifel RCP FeLV*	Merial	EU/2/02/031/001-002	0.00149	1.5 per 100,00 doses	08/03/2002	31/03/2006
Feligen RCP	Virbac S.A.	05653/4048	0.00062	0.6 per 100,000 doses	01/01/1993	30/06/2009
Felocell CVR	Eli Lilly & Co. Ltd	00006/4123	0.00085	0.9 per 100,000 doses	01/08/1989	30/06/2009
Fevaxyn FeLV	Pfizer Ltd	00057/4320	0.00039	0.4 per 100,000 doses	01/06/1995	28/04/2009
Fevaxyn iCHP	Pfizer Ltd	00057/4318	0.00030	0.3 per 100,000 doses	01/07/2000	31/01/2009

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Product Name	MA Holder	MA Number	Incidence Rate (%)	Incidence Explanation	Start Date	End Date
Fevaxyn Pentofel, Solution for Injection, for Cats	Pfizer Ltd	EU/2/96/002/001-003	0.00126	1.3 per 100,000 doses	05/02/1997	30/06/2009
Katavac CHP	Pfizer Ltd	00057/4304	0.00006	0.06 per 100,000 doses	01/01/1992	28/02/2010
Katavac Eclipse	Pfizer Ltd	00057/4319	0.00079	0.8 per 100,000 doses	28/07/1995	30/06/2008
Leucogen Suspension for Injection for Cats	Virbac S.A.	EU/2/09/096/001-002	0.00040	0.4 per 100,000 doses	01/01/1989	31/01/2011
Leukocell 2	Pfizer Ltd	00057/4114	0.00131	1.3 per 100,000 doses	01/08/1993	30/04/2009
Nobivac FeLV	Virbac S.A.	05653/4059	0.00146	1.5 per 100,000 doses	01/11/2005	31/10/2009
Nobivac Forcat	Intervet International BV	06376/4050	0.00067	0.7 per 100,000 doses	22/12/2005	31/12/2009
Nobivac Rabies	Intervet UK Ltd	01708/4325	0.00037	0.4 per 100,000 doses	01/09/1987	30/11/2008
Nobivac Tricat*	Intervet UK Ltd	01708/4514	0.00072	0.7 per 100,000 doses	01/01/1986	31/03/2008
Nobivac Tricat Trio	Intervet UK Ltd	01708/4533	0.00100	1.0 per 100,000 doses	21/06/2006	30/06/2010
Purevax FeLV**	Merial	EU/2/00/019/005-007	0.00199	2.0 per 100,000 doses	01/04/2000	31/10/2010
Purevax RCP	Merial	EU/2/04/052/001-002	0.00026	0.3 per 100,000 doses	23/02/2005	28/02/2009
Purevax RCP FeLV	Merial	EU/2/04/048/001-002	0.00083	0.8 per 100,000 doses	23/02/2005	28/02/2009
Purevax RCPCh FeLV	Merial	EU/2/04/047/001-002	0.00098	1.0 per 100,000 doses	23/02/2005	28/02/2009
Quantum Cat CVRP	Intervet UK Ltd	01708/4557	0.00040	0.4 per 100,000 doses	01/01/1995	31/12/2009
Quantum Cat FeLV	Intervet UK Ltd	01708/4561	0.00095	1.0 per 100,000 doses	01/01/1996	31/12/2009

** denotes Marketing Authorisations which have now expired*

** * name changed from Eurifel FeLV in May 2005*