

FOI 15-1465

CAERS Reports Allegedly Related to Prevagen Products by Quincy Bioscience

Search Terms: Products Listed

FDA's Center for Food Safety and Applied Nutrition's (CFSAN's) Adverse Event Reporting System (CAERS) is a post-market surveillance system that collects reports about adverse events and product complaints that are allegedly related to CFSAN-regulated products. These products include conventional foods (and beverages), dietary supplements, infant formulas and cosmetics.

The adverse event reports about a product and the total number of adverse event reports for that product in CAERS only reflect information AS REPORTED and do not represent any conclusion by FDA about whether the product actually caused the adverse events. The attached reports are what have been entered into CAERS during the requested dates (the search date used was the CAERS entered date, as opposed to other dates such as the FDA Received Date or CAERS Received Date, etc.).

The reports submitted to FDA vary in the quality and reliability of the information provided. Some reports to FDA do not necessarily include all relevant data, such as whether an individual also suffered from other medical conditions or used other products or medications at the same time. Reports may not include accurate or complete contact information for FDA to seek further information about the event, or complainants may choose not to participate in a follow-up investigation. When important information is missing from a report, it is difficult for FDA to fully evaluate whether the product caused the adverse event or simply coincided with it. There also may be duplicate reports in CAERS for the same adverse event because multiple people (such as an injured consumer and a health care provider who treated him or her) may have submitted reports.

Because CAERS is constantly updated with new information, the number of reports for a given product and the content of individual reports may change over time.

Report #	RA CAERS Created Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
129147	08/19/2010	PREVAGEN (APOAEQUORIN) 10 MG	QUINCY BIOSCIENCE	DIZZINESS, ALTERED VISUAL DEPTH PERCEPTION	HOSPITALIZATION
141869	07/28/2011	PREVAGEN (APOAEQUORIN) 10MG	QUINCY BIOSCIENCE	CONVULSION	HOSPITALIZATION
	07/28/2011	PREVAGEN (APOAEQUORIN) 10MG	QUINCY BIOSCIENCE	CONVULSION	HOSPITALIZATION
146177	11/30/2011	PREVAGEN 10 MG	QUINCY BIOSCIENCE	CONVULSION	HOSPITALIZATION
147289	01/03/2012	PREVAGEN	QUINCY BIOSCIENCE	BRAIN NEOPLASM, CEREBROVASCULAR ACCIDENT, RENAL DISORDER, GOUT, HYPERTENSION, DIABETES MELLITUS, OBESITY, RENAL IMPAIRMENT, THROMBOSIS, GAIT DISTURBANCE, SPEECH DISORDER	HOSPITALIZATION
	01/03/2012	PREVAGEN	QUINCY BIOSCIENCE	BRAIN NEOPLASM, CEREBROVASCULAR ACCIDENT, RENAL DISORDER, GOUT, HYPERTENSION, DIABETES MELLITUS, OBESITY, RENAL IMPAIRMENT, THROMBOSIS, GAIT DISTURBANCE, SPEECH DISORDER	HOSPITALIZATION
147887	01/20/2012	PREVAGEN ES 20 MG	QUINCY BIOSCIENCE	MYOCARDIAL INFARCTION	LIFE THREATENING, HOSPITALIZATION
147888	01/20/2012	PREVAGEN PROFESSIONAL 20 MG	QUINCY BIOSCIENCE	BRADYCARDIA, ARRHYTHMIA, TACHYCARDIA, DIZZINESS	HOSPITALIZATION
147902	01/20/2012	PREVAGEN 10 MG	QUINCY BIOSCIENCE	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION

Report #	RA_CAERS Created Date	Brand/Product Name	PRM_Firm Name	Symptoms	Outcomes
147904	01/20/2012	PREVAGEN PROFESSIONAL 40 MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT, GAIT DISTURBANCE, DYSPNOEA, HEADACHE	HOSPITALIZATION
147905	01/20/2012	PREVAGEN PROFESSIONAL 10 MG	QUINCY BIOSCIENCE	NEUROLOGICAL SYMPTOM	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
147906	01/20/2012	PREVAGEN 10 MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
147907	01/20/2012	PREVAGEN 10 MG	QUINCY BIOSCIENCE	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
147908	01/20/2012	PREVAGEN 10 MG	QUINCY BIOSCIENCE	CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
148320	01/31/2012	PREVAGEN ES	QUINCY BIOSCIENCE	GLIOBLASTOMA MULTIFORME	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
148685	02/10/2012	PREVAGEN PROFESSIONAL 40 MG	QUINCY BIOSCIENCE	HYPOTENSION, DEPRESSED LEVEL OF CONSCIOUSNESS, DEPRESSED LEVEL OF CONSCIOUSNESS	HOSPITALIZATION
149110	02/22/2012	PREVAGEN	QUINCY BIOSCIENCE	RENAL DISORDER, BLOOD CREATININE INCREASED, DRUG INTERACTION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
149959	03/14/2012	PREVAGEN PROFESSIONAL 40 MILIGRAMS	QUINCY BIOSCIENCE	PAPILLOMA, INTRADUCTAL PAPILLOMA OF BREAST, BLOODY DISCHARGE	HOSPITALIZATION
152915	06/01/2012	QUINCY BIOSCIENCE PREVAGEN 10 MG	QUINCY BIOSCIENCE	HYPERTENSION, BLOOD PRESSURE INCREASED	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
154742	07/25/2012	PREVAGEN EXTRA STRENGTH 20 MG	QUINCY BIOSCIENCE	MULTIPLE SCLEROSIS RELAPSE	HOSPITALIZATION
	07/25/2012	PREVAGEN PROFESSIONAL 40 MG	QUINCY BIOSCIENCE		
156196	09/07/2012	PREVAGEN PROFESSIONAL	QUINCY BIOSCIENCE	ANEURYSM, HAEMORRHAGE INTRACRANIAL	DEATH
162504	02/21/2013	PREVAGEN, 10MG, QUINCY BIOSCIENCE	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT	HOSPITALIZATION, DISABILITY

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163742	03/25/2013	PREVAGEN 10 MG	QUINCY BIOSCIENCE	OSTEOPOROSIS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
165501	05/14/2013	PREVAGEN 10MG	QUINCY BIOSCIENCE	ABDOMINAL PAIN, PAIN	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
169807	09/09/2013	PREVAGEN, 10 MG	QUINCY BIOSCIENCE	LOSS OF CONSCIOUSNESS, FEELING ABNORMAL, SPEECH DISORDER	HOSPITALIZATION
170983	10/22/2013	PREVAGEN EXTRA STRENGTH, 200MG, QUINCY BIOSCIENCE	QUINCY BIOSCIENCE	HYPERCALCAEMIA, BLOOD CALCIUM INCREASED	LIFE THREATENING, HOSPITALIZATION
170984	10/22/2013	PREVAGEN, 10 MG, BIOSCIENCE	QUINCY BIOSCIENCE	CHEST PAIN, MYOCARDIAL INFARCTION	VISITED AN ER, HOSPITALIZATION
171717	11/05/2013	PREVAGEN, 10MG	QUINCY BIOSCIENCE	ISCHAEMIA, CEREBROVASCULAR ACCIDENT	HOSPITALIZATION
172204	11/26/2013	QUINCY BIOSCIENCE PREVAGEN, ES, 20MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT, TRANSIENT ISCHAEMIC ATTACK	HOSPITALIZATION
172228	11/27/2013	PREVAGEN, 10MG, QUINCY BIOSCIENCE	QUINCY BIOSCIENCE	HEART RATE IRREGULAR, BLOOD PRESSURE INCREASED, HYPERTENSION, CHEST PAIN, ATRIAL FIBRILLATION	LIFE THREATENING, HOSPITALIZATION
172963	01/02/2014	PREVAGEN, 10MG	QUINCY BIOSCIENCE	FLATULENCE, DIVERTICULITIS, COLITIS, VOMITING, NAUSEA	HOSPITALIZATION
173718	02/05/2014	PREVAGEN ES, 20MG	QUINCY BIOSCIENCE	GLOBAL AMNESIA	HOSPITALIZATION
175282	04/07/2014	PREVAGEN 10MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT	HOSPITALIZATION
175283	04/07/2014	PREVAGEN EXTRA STRENGTH 20MG	QUINCY BIOSCIENCE	HALLUCINATION	HOSPITALIZATION
175526	04/14/2014	PREVAGEN EXTRA STRENGTH 20 MG	QUINCY BIOSCIENCE	LETHARGY, PRODUCTIVE COUGH	HOSPITALIZATION
176937	06/05/2014	QUINCY BIOSCIENCE PREVAGEN 10MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT, DIZZINESS, MEMORY IMPAIRMENT, HYPERTENSION, DYSPEPSIA, VISION BLURRED	HOSPITALIZATION
177403	06/25/2014	PREVAGEN	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT, DIPLOPIA, EYE DISORDER	HOSPITALIZATION

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177667	07/07/2014	QUINCY BIOSCIENCE PREVAGEN	QUINCY BIOSCIENCE	HEPATIC FUNCTION ABNORMAL, CHILLS, FALL, HEPATOBILIARY DISEASE	HOSPITALIZATION
179566	09/25/2014	PREVAGEN ES 20 MG	QUINCY BIOSCIENCE	ANAEMIA, DYSPNOEA, HAEMOGLOBIN DECREASED	HOSPITALIZATION
179829	10/07/2014	PREVAGEN 10MG QUINCY BIOSCIENCE	QUINCY BIOSCIENCE	DIZZINESS, PERICARDIAL EFFUSION	HOSPITALIZATION
180571	11/05/2014	QUINCY BIOSCIENCE - PREVAGEN 10MG	QUINCY BIOSCIENCE	BLINDNESS, VISUAL IMPAIRMENT, CATARACT	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
180572	11/05/2014	QUINCY BIOSCIENCE - PREVAGEN 10MG	QUINCY BIOSCIENCE	CONVULSION	VISITED A HEALTH CARE PROVIDER, HOSPITALIZATION
180791	11/14/2014	PREVAGEN 10MG	QUINCY BIOSCIENCE	CEREBROVASCULAR ACCIDENT	HOSPITALIZATION
180908	11/19/2014	PREVAGEN, 10MG	QUINCY BIOSCIENCE MANUFACTURING INC.	CHEST PAIN, CEREBROVASCULAR ACCIDENT	HOSPITALIZATION
181189	12/05/2014	PREVAGEN 10 MG	QUINCY BIOSCIENCE	FALL	HOSPITALIZATION
182056	01/20/2015	PREVAGEN 10MG CAPSULES	QUINCY BIOSCIENCE	URTICARIA, GRAND MAL CONVULSION, CONVULSION	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
182145	01/26/2015	QUINCY BIOSCIENCE PREVAGEN 10 MG	QUINCY BIOSCIENCE	HYPOTENSION	HOSPITALIZATION
182237	01/28/2015	PREVAGEN APOAEQUORIN EXTRA STRENGTH	QUINCY BIOSCIENCE MANUFACTURING INC.	CONVULSION	VISITED AN ER, HOSPITALIZATION
182453	01/30/2015	QUINCY BIOSCIENCE PREVAGEN	QUINCY BIOSCIENCE	DEPRESSED MOOD, ALOPECIA, STRESS	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS)
182859	02/09/2015	PREVAGEN 10MG	QUINCY BIOSCIENCE	DYSPNOEA, PNEUMONIA	OTHER SERIOUS (IMPORTANT MEDICAL EVENTS), HOSPITALIZATION
182860	02/09/2015	QUINCY BIOSCIENCE PREVAGEN 10MG	QUINCY BIOSCIENCE MANUFACTURING INC.	CEREBROVASCULAR ACCIDENT	HOSPITALIZATION

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183076	02/19/2015	PREVAGEN	QUINCY BIOSCIENCE	CHEST PAIN, DIZZINESS, BALANCE DISORDER, ABDOMINAL PAIN UPPER, MALAISE, VISION BLURRED	VISITED A HEALTH CARE PROVIDER, LIFE THREATENING
183378	03/03/2015	PREVAGEN ES 20MG	NOT AVAILABLE		HOSPITALIZATION
	03/03/2015	PREVAGEN ES 20MG	NOT AVAILABLE		HOSPITALIZATION
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