

Safety Alert

Oct 2023

Statins - risk of Myasthenia Gravis

EDA performs label update to include the following:

Special warnings and precautions for use

Myasthenia gravis in few cases, statins have been reported to **induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia**. statins should be discontinued in case of aggravation of symptoms. Recurrences when the same or a different statin was (re-) administered have been reported.

Undesirable effects

System Organ Class	Adverse reactions (fenofibrate)	Adverse reactions (simvastatin)	Frequency
Nervous system disorders	Headache		uncommon
		Paresthesia, dizziness, peripheral neuropathy	rare
		Memory impairment/ Memory loss	rare
		Myasthenia gravis	not known
Eye disorders		Vision blurred, visual impairment	rare
		Ocular myasthenia	not known

Background:

Myasthenia gravis (MG) is a chronic autoimmune disorder in which antibodies destroy the communication between nerves and muscle, resulting in weakness of the skeletal muscles. Myasthenia gravis affects the voluntary muscles of the body, especially those that control the eyes, mouth, throat and limbs.

References:

EMA ([Click here](#))