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SFDA Drug Safety communication

Potential Risk of Myasthenia Gravis with Statins

Key messages

- There is a potential risk of new-onset or aggravation of pre-existing myasthenia gravis with the use of statins.
- This risk was identified through post-marketing medication safety monitoring, review of data from regulatory agencies and an evaluation of medical literature.
- SFDA recommends healthcare providers to monitor patients on statins for any new symptoms of myasthenia gravis and advise patients accordingly.
- SFDA is not recommending any changes to the use of statins at this time, but is communicating this information to raise awareness among healthcare providers.

Statins, such as atorvastatin, pravastatin, fluvastatin, simvastatin, rosuvastatin, and pitavastatin (both single-ingredient and fixed-dose combination products), belong to a class of drugs called hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors. These medications are primarily used to lower cholesterol levels and prevent cardiovascular diseases by inhibiting the enzyme HMG-CoA reductase, which plays a central role in cholesterol production in the liver.

The safety concern identified is a potential risk that statins could cause new-onset myasthenia gravis or exacerbate pre-existing myasthenia gravis in some patients. Myasthenia gravis is a long-term autoimmune neuromuscular disorder characterized by fluctuating weakness in the voluntary muscles responsible for eye movements, facial expression, speech, swallowing, limb movement, and breathing. Symptoms of myasthenia gravis may include drooping eyelids, double vision, difficulties with chewing or swallowing, speech problems, limb weakness, and shortness of breath. This risk has been reported globally in a number of post-marketing case reports, with symptoms typically resolving after discontinuation of statin therapy. The

identification of this potential risk was made through post-marketing medication safety monitoring, review of data from regulatory agencies, and evaluation of medical literature.

The SFDA recognizes the important role of statins in managing cholesterol levels and preventing cardiovascular diseases. Currently, there are no recommended changes to the use of these medications. Despite the low frequency of occurrence, considering the widespread use of statins, it is crucial to monitor patients who are taking these medications. Healthcare professionals are urged to remain vigilant for clinical signs and symptoms suggestive of myasthenia gravis and to consider referring patients to a neurologist when necessary.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Call Center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>