

SB TITCK 08.06.2023 STATINLER İLE İLİŞKİLİ MYASTHENIA GRAVIS VE OKÜLER MYASTENİ_EN

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REPUBLIC OF TÜRKİYE MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency
08.06.2023 Number : E-24931227-510.01.04-1131451 Subject : Statins/Myasthenia gravis and ocular myasthenia/ Urgent Safety Restriction/Opinion-Contribution

DOSSIER

The warning titled “3-hydroxy 3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins): atorvastatin; fluvastatin; lovastatin; pitavastatin; pravastatin; rosuvastatin; simvastatin and other relevant fixed dose combinations; pravastatin, fenofibrate; simvastatin, fenofibrate – Myasthenia gravis” published on the official website of the European Medicines Agency on 06 February 2023 regarding the risk of Myasthenia gravis and ocular myasthenia of all drugs in the statin group states that the product information of medicinal products containing atorvastatin, pravastatin, lovastatin, fluvastatin, simvastatin, rosuvastatin and pitavastatin, both as single component and in fixed dose combinations, will be updated. You are required to add the statements in the annex to the summary of product characteristics (SmPC) and patient information leaflet (PIL) of the medicinal products licensed in Türkiye. You are kindly requested to share your opinions, recommendations and contributions, if any, regarding the decision taken to the Department of Pharmacovigilance and Agents Subject to Control, Pharmacovigilance Risk Management Unit by 19.06.2023, and not apply to the Pharmacological Evaluation Unit within this period.

Dr. Asım HOCAOĞLU Agency President

Annex1: Union Association Announcement (1 page) Appendix2: https://www.ema.europa.eu/en/documents/prac-recommendation/prac-recommendations-signals-adopted-9-12-january-2023-prac-meeting_en.pdf

Distribution: To: Pharmaceutical Industry Association of Türkiye Association of Researched-based Pharmaceutical Companies Pharmaceutical Manufacturers Association of Türkiye Healthcare Products Association

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[The following statements should be included in the summary of product characteristics and patient information leaflets of all statin-containing medicines.]

SUMMARY OF PRODUCT CHARACTERISTICS

4.4. Special warnings and precautions for use Myasthenia gravis In a small number of cases, statins have been reported to induce new-onset myasthenia gravis or ocular myasthenia or exacerbate pre-existing myasthenia gravis or ocular myasthenia (see section 4.8). In case of exacerbation of symptoms <Name of the drug product> should be discontinued. Relapses have been reported when the same or a different statin is (re)administered.

4.8. Undesirable effects Tabulated list of adverse reactions

MedDRA Standard System Organ Class Adverse reactions Frequency Nervous System Disorders Myasthenia gravis unknown Eye Disorders Ocular myasthenia unknown

PATIENT INFORMATION LEAFLET

2. BEFORE YOU USE <Name of the drug product> TAKE SPECIAL CARE with <Name of the drug product> • If you currently have or ever had myasthenia (a disease characterised by generalised muscle weakness, including the muscles used for breathing in some cases) or ocular myasthenia (a disease that causes weakness in the eye muscles), statins can sometimes aggravate the condition or lead to the development of myasthenia. (see section 4) 4. POSSIBLE SIDE EFFECTS Unknown: • Myasthenia gravis (a disease that causes generalised muscle weakness, including the muscles used for breathing in some cases). Ocular myasthenia (a disease that causes weakness in the eye muscles). Consult your doctor if you experience weakness in your arms or legs that worsens after movement, difficulty swallowing, shortness of breath, drooping eyelids or double vision.

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