Notice: Market withdrawal of batch 4L01372N of the medicinal product Fingolimod Zentiva 0.5 mg capsules

Through a notification received from the Marketing Authorization Holder (MAH) "Zentiva Kosovo Medicines Agency (KMA) has been informed of the voluntary market withdrawal of batch 4L01372N of the medicinal product Fingolimod Zentiva 0.5 mg capsules; a total of 243 boxes of this batch were imported into the Republic of Kosovo.

The market withdrawal was initiated due to a deviation identified during the manufacturing process at the Labormed Pharma S.A. plant, a company within the Zentiva Group.

According to information provided by the manufacturer, individual results obtained from AQL (Acceptable Quality Limit) testing for batch 4L01372N fell within established acceptance criteria. Furthermore, based on the characterization of the identified particles, their size was estimated to be below the detection threshold of the metal detector, and the manufacturer's assessment identified no potential impact on patient safety.

However, considering the cumulative results obtained from testing various batches of the finished product, Labormed Pharma S.A. has decided to proceed with the voluntary market withdrawal of finished product batches produced from bulk batch 4L01372.

Advice for patients

Patients who are using or have used the product Fingolimod Zentiva 0.5 mg capsules (batch number 4L01372N) and have experienced any adverse effect or concern after using the product should contact their doctor, pharmacist, or other healthcare professional. Advice for healthcare professionals

Healthcare professionals who have received reports regarding a suspected adverse effect following the use of Fingolimod Zentiva 0.5 mg capsules (batch number 4L01372N) are encouraged to report such cases to the local person responsible for pharmacovigilance, authorized by the Marketing Authorization Holder "Zentiva," at the following address:

E-mail: pharmacovigilance@pharmakos.biz

Suspected adverse reactions/effects may also be reported directly to the AKPPM using the standard CIOMS form for reporting suspected adverse reactions—available on the AKPPM website—or via the following address:

E-mail: info.akppm@rks-gov.net

The AKPPM advises healthcare professionals to include as much relevant information as possible regarding the patient, the medicinal product, the batch number, and the suspected adverse reaction/effect when submitting a report.

Kosovo Medicines Agency (KMA)