Fenspiride, EURESPAL 80 mg, coated tablet and EURESPAL 0.2 per cent, syrup
Withdrawal from the market in Armenia

Dear Healthcare professional,

In agreement with the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan, Les Laboratoires Servier would like to inform you of fenspiride (Eurespal 80 mg, coated tablet and Eurespal 0.2 per cent, syrup) withdrawal from the market based on new nonclinical safety information:

Summary

- The decision to withdraw from the market its fenspiride containing medicinal products is based on new non-clinical safety data showing a potential for QT interval prolongation.

- Although the clinical relevance of these new findings has not been fully elucidated, as a precautionary measure and in the interest of patients' safety, Les Laboratoires Servier in agreement with Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan has decided to withdraw its fenspiride containing products from the market.

- Fenspiride-containing medicinal products will no longer be available from 28th February 2019 and a batch recall will be carried out at this date.

- Healthcare professionals are advised:
  - to stop prescribing or dispensing EURESPAL
  - to inform the patients about alternative therapy,
  - to tell their patients to stop taking EURESPAL and to return their EURESPAL remaining treatment to their pharmacies.

Background on the safety concern

EURESPAL is a prescription only medicine containing the active ingredient fenspiride, and is used to treat symptoms (cough and expectoration) occurring during the course of bronchopulmonary diseases. EURESPAL was first registered in 1973 in France and is currently marketed in 32 countries.

In 2018, further to the review of cumulative safety data from post-marketing experience by the Pharmacovigilance Risk Assessment Committee (PRAC), committee at the European Medicines Agency (EMA) responsible for assessing and monitoring safety issues for human medicines, Les Laboratoires Servier conducted experimental studies (hERG channel binding study and guinea pigs isolated heart study) to evaluate the pro-arrhythmogenesis potential of fenspiride: these results have shown the potential of QT interval prolongation by fenspiride.

Since fenspiride was first marketed in 1973, 5 post-marketing cases of QT prolongation (3 of them associated with torsade de pointes) were reported worldwide, all with a favourable outcome.

In the light of the new non-clinical safety data and considering that fenspiride is used to treat non-life-threatening functional symptoms for which alternative treatments are available, Les Laboratoires Servier in agreement with the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan decided to withdraw its fenspiride containing medicinal products from the market as a precautionary measure.

Call for reporting

Please report suspected adverse drug reactions (ADRs) to the Scientific Centre of Drug and Medical Technology Expertise after academician Emil Gabrielyan, www.pharm.am; vigilance@pharm.am tel.: +374 10 23 72 65, +374 96 22 05 05, postal address: 49/4 Komitas aven., Yerevan 0051, Armenia and to the Armenia Representative Office of Les Laboratoires Servier, Local Responsible person for Pharmacovigilance Mariam Antonyan, tel: +374 91 03 20 80, +374 10 50 50 74, e-mail: mariam.antonyan@servier.com, postal address: 1 Hyusisain Ave., «NORD» Business Centre, 3rd floor, 0001 Yerevan, Armenia.

Company contact point

For further inquiries concerning this information, please contact the Armenia Representative Office of Les Laboratoires Servier, Local Responsible person for Pharmacovigilance Mariam Antonyan, tel: +374 91 03 20 80, +374 10 50 50 74, e-mail: mariam.antonyan@servier.com, postal address: 1 Hyusisain Ave., «NORD» Business Centre, 3rd floor, 0001 Yerevan, Armenia.