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RECERTIFICATION REQUIRED

KYNAMRO REMS Program Changes For Healthcare Professionals

Dear Healthcare Professional:

This letter is to inform you of recent changes in the KYNAMRO® (mipomersen sodium) injection Risk Evaluation and Mitigation Strategy (REMS) Program. To continue to prescribe KYNAMRO, **healthcare professionals must recertify** in the KYNAMRO REMS Program by April 1, 2018.

Action Required

All currently enrolled healthcare professionals must recertify by April 1, 2018 in order to continue to prescribe KYNAMRO. To recertify in the KYNAMRO REMS Program, healthcare professionals must:

- **Review** the KYNAMRO Prescribing Information and the *KYNAMRO REMS Program: An Introduction*.
- **Complete** the updated *KYNAMRO REMS Program Certification Training Module* and successfully complete the Knowledge Assessment.
- **Enroll** in the KYNAMRO REMS program by completing the *KYNAMRO REMS Program Prescriber Enrollment Form* and submit to the KYNAMRO REMS Program Coordinating Center.

How To Enroll or Recertify in the KYNAMRO REMS Program

- Call the KYNAMRO REMS Program Coordinating Center at 1-877-596-2676.
- Contact your Kastle Clinical Science Specialist.
- Learn more at www.KYNAMROREMS.com **KYNAMRO REMS Program Changes.**

The KYNAMRO REMS Program now has additional requirements for both healthcare professionals and patients. Before prescribing KYNAMRO you must:

1. **Review** the *KYNAMRO REMS Program Patient Guide* with each patient to counsel the patient about the appropriate use and risks associated with KYNAMRO and provide a copy to the patient.
2. **Complete** the KYNAMRO REMS *Program Patient - Prescriber Acknowledgment Form* with each patient, and submit it to the KYNAMRO REMS Program Coordinating Center.
3. **Prescribe** KYNAMRO for each patient by completing the *KYNAMRO REMS Program Prescription Authorization Form* and submit to the KYNAMRO REMS Program Coordinating Center.

Please see the accompanying Prescribing Information for your reference. As always, please report any adverse events to Kastle Drug Info at 1- 877-279-2308 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Sincerely,

Stuart Kupfer
Chief Medical Advisor, Kastle Therapeutics