



1.0 Goals

The goal of the REMS is to inform patients of the serious risks associated with the use of Kaletra, including the risk of potential cardiac arrhythmias.

2.0 REMS Elements

2.1 Medication Guide

A Medication Guide will be dispensed with each Kaletra Tablet and Kaletra Oral Solution prescription. Kaletra Tablets and Kaletra Oral Solution are sold in unit-of-use packaging whereby the approved U.S. package insert containing the Medication Guide will be included with each unit-of-use package. This will permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for Kaletra. In addition, the Kaletra package insert containing the Medication Guide will be made available via the internet at www.KALETRA.com.

Additionally, in accordance with 21 CFR §208.24(d), the Kaletra Tablet container labels and the Kaletra Oral Solution carton and container labels will alert pharmacists to dispense the Medication Guide with the product.

2.2 Timetable for Submission of Assessments

- 1st FDAAA assessment: October 2010 (18 months from initial REMS approval)
- 2nd FDAAA assessment: April 2012 (3 years from initial REMS approval)
- 3rd FDAAA assessment: April 2016 (7 years from initial REMS approval)