

NDA 20-636 VIRAMUNE (nevirapine) Tablets

NDA 20-933 VIRAMUNE(nevirapine) Oral Suspension

Non-nucleoside reverse transcriptase inhibitor (NRTI) with activity against Human Immunodeficiency Virus Type 1.

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RISKEVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of VIRAMUNE (nevirapine)

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each VIRAMUNE prescription. The VIRAMUNE (nevirapine) Medication Guide is included in the packaging for VIRAMUNE (nevirapine) tablets and oral suspension. The current packaging for VIRAMUNE (nevirapine) is considered unit-of-use.

B. Timetable for Submission of Assessments

Boehringer Ingelheim Pharmaceuticals Inc. will submit REMS Assessments to FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Boehringer Ingelheim Pharmaceuticals Inc. will submit each assessment so that it will be received by the FDA on or before the due date.