

I. Goals

The goals of the Tyzeka REMS are:

1. To increase patient awareness of the potential for peripheral neuropathy to occur with Tyzeka treatment.
2. To raise patient awareness of the increased risk of developing peripheral neuropathy when Tyzeka is used in combination with pegylated interferon alfa-2a or other interferons.

II. REMS Elements

A. Medication Guide

Novartis has developed a medication guide to be distributed to patients taking Tyzeka.

Novartis will include a medication guide with each Tyzeka finished package. Medication guides will be included in each carton containing a bottle of Tyzeka; there will be instructions on the carton and container label to the pharmacist instructing that the medication guide be distributed with the dispensed product.

Novartis will conduct patient surveys to confirm distribution and understanding of the medication guide.

The Medication Guide is appended to the REMS.

B. Communication Plan

The REMS for Tyzeka does not include a specific Communication Plan.

C. Elements Regarding Safe Use

The REMS for Tyzeka does not include elements to assure safe use.

D. Implementation System

Because the REMS for Tyzeka (telbivudine) does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

The Tyzeka REMS will be evaluated periodically with formal assessments as described in Table 1.

Table 1 Timetable for REMS Assessments

1 st Assessment	July 2010	18 months post-approval
2 nd Assessment	January 2012	3 years post-approval
3 rd Assessment	January 2016	7 years post-approval