An amber syringe and cap are provided for dosing, and the product may be kept in the syringe for a maximum of 24 hours at room temperatures up to 25°C (77°F) or refrigerated at 2°C to 8°C (36°F to 46°F). The syringe should be discarded after one use. After dilution, the preparation should be used immediately.

Rapamune Oral Solution provided in bottles may develop a slight haze when refrigerated. If such a haze occurs, allow the product to stand at room temperature and shake gently until the haze disappears. The presence of this haze does not affect the quality of the product.

16.2 Rapamune Tablets

Rapamune Tablets are available as follows:

- NDC 0008-1040-05, 0.5 mg, tan, triangular-shaped tablets marked “RAPAMUNE 0.5 mg” on one side; bottle containing 100 tablets.
- NDC 0008-1040-10, 0.5 mg, tan, triangular-shaped tablets marked “RAPAMUNE 0.5 mg” on one side; in Redipak® cartons of 100 tablets (10 blister cards of 10 tablets each).
- NDC 0008-1041-05, 1 mg, white, triangular-shaped tablets marked “RAPAMUNE 1 mg” on one side; bottle containing 100 tablets.
- NDC 0008-1041-10, 1 mg, white, triangular-shaped tablets marked “RAPAMUNE 1 mg” on one side; in Redipak® cartons of 100 tablets (10 blister cards of 10 tablets each).
- NDC 0008-1042-05, 2 mg, yellow-to-beige triangular-shaped tablets marked “RAPAMUNE 2 mg” on one side; bottle containing 100 tablets.

Rapamune Tablets should be stored at 20° to 25°C [USP Controlled Room Temperature] (68° to 77°F). Use cartons to protect blister cards and strips from light. Dispense in a tight, light-resistant container as defined in the USP.

17 PATIENT COUNSELING INFORMATION

Advise patients, their families, and their caregivers to read the Medication Guide and assist them in understanding its contents. The complete text of the Medication Guide is reprinted at the end of the document.

See FDA-Approved Medication Guide.

17.1 Dosage

Patients should be given complete dosage instructions [*see FDA-Approved Medication Guide*].

17.2 Skin Cancer Events

Patients should be told that exposure to sunlight and ultraviolet (UV) light should be limited by wearing protective clothing and using a sunscreen with a high protection factor because of the increased risk for skin cancer [*see Warnings and Precautions (5.17)*].

17.3 Pregnancy Risks

Women of childbearing potential should be informed of the potential risks during pregnancy and told that they should use effective contraception prior to initiation of Rapamune therapy, during Rapamune therapy, and for 12 weeks after Rapamune therapy has been stopped [*see Use in Specific Populations (8.1)*].