10 March 2025

IMPORTANT DRUG INFORMATION

Subject: **TAVALISSE® (fostamatinib), Revised Guidance Pertaining to the Storage and Handling of TAVALISSE**

Dear Health Care Provider,

The purpose of this letter is to inform you of important information and revised guidance pertaining to the storage and handling of TAVALISSE (fostamatinib).

Background

TAVALISSE is currently supplied as follows:

TAVALISSE 100 mg tablets are round, biconvex, orange, film-coated tablets debossed with "100" on one side and "R" on the reverse side.

TAVALISSE 150 mg tablets are oval, biconvex, orange, film-coated tablets debossed with "150" on one side and "R" on the reverse side.

100 mg tablets: Available in bottle of 60 with 2 desiccant canisters NDC 71332-001-01

150 mg tablets: Available in bottle of 60 with 2 desiccant canisters NDC 71332-002-01

The current storage instructions contained within the prescribing information lists the following:

Store at room temperature, 20º C to 25º C (68º F to 77º F); excursions permitted between 15º C to 30º C (59º F to 86º F) [see USP Controlled Room Temperature]. Do not remove desiccants.

To minimize the potential risk of administration of degraded drug product, the following updates to the storage instructions will be included in Section 16 (*HOW SUPPLIED/STORAGE AND HANDLING)* and the Patient Information (*How should I store TAVALISSE?*) sections of the Full Prescribing Information and Patient Package Insert:

- *Store TAVALISSE at room temperature between 68°F and 77°F (20°C to 25°C).*
- *Keep TAVALISSE in the bottle that it comes in.*
- *The bottle of TAVALISSE contains 2 desiccant canisters that help keep your medicine dry. Do not remove the desiccant canisters from the bottle.*
- *Throw away (discard) any unused TAVALISSE tablets after 60 days of opening the bottle.*

The corresponding updates to the prescribing information and container labels will be forthcoming.

Prescriber Action

Health care providers should inform their patients, pharmacists, staff and any provider in their institution who may be involved in the administration of TAVALISSE of the updated guidance on the storage and handling.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients taking TAVALISSE to Rigel Pharmaceuticals, Inc. at 1-800-983-1329 or producthelp@rigel.com. Adverse events or quality problems experienced with the use of this product may also be reported to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Company Contact Point

You may also contact our medical information department at 1-800-983-1329 or producthelp@rigel.com if you have any questions about the information contained in this letter or the safe and effective use of TAVALISSE.

This letter is not intended as a complete description of the benefits and risks related to the use of TAVALISSE. Please refer to the accompanying Full Prescribing Information and patient package insert or visit www.tavalissehcp.com for more information.

Sincerely,

Lisa Rojkjaer

Lisa Rojkjaer, MD
Executive Vice President, Chief Medical Officer

Enclosure(s): TAVALISSE (fostamatinib) Full Prescribing Information/Patient Prescribing Information

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