Knight Therapeutics (USA), Inc.
(888) 376-7830 (x5367)
c/o The Corporation Trust Company, Corporation Trust Center
1209 Orange Street
Wilmington, DE

May 2, 2025

IMPORTANT PRESCRIBING INFORMATION

Subject:	Temporary Extension of Expiry Dating of One Batch (4B8114) of Impavido (miltefosine) 50mg Capsules to prevent a shortage of this product in the U.S.

Dear Health Care Provider,

To alleviate limited availability of Impavido® (miltefosine) 50mg Capsules, Knight Therapeutics (USA), Inc has coordinated with the Food and Drug Administration (FDA) to extend the expiry date of a single lot (4B8114) of Impavido® (miltefosine) 50mg Capsule (NDA 204684) from 24 months to 36 months without relabeling the product. Impavido (miltefosine) 50 mg Capsules will be temporarily out of stock due to a delay in the manufacturing of a new batch. A new batch is expected to be available before July 31, 2026. Impavido is distributed by Profounda Inc.

Important Batch Information

Impavido (miltefosine) 50 mg Capsules is indicated for the treatment of adults and adolescents ≥ 12 years of age weighing greater than or equal to 30 kg (66 lbs) with Leishmaniasis.

Batch #4B8114 was originally labeled with a 24-month shelf life, expiring on July 31, 2025. However, based on supportive stability data previously submitted to the FDA demonstrating a 36-month shelf life for prior batches, the expiration date for this batch has now been extended to July 31, 2026.

SUMMARY:

- Impavido (miltefosine) 50 mg capsule
- Batch #4B8114
- Current labeled expiration date: July 31, 2025
- Extended expiration date: July 31, 2026

Knight Therapeutics (USA), Inc.
(888) 376-7830 (x5367)
c/o The Corporation Trust Company, Corporation Trust Center
1209 Orange Street
Wilmington, DE

Reporting Adverse Events

Healthcare providers should report adverse events associated with the use of Impavido (miltefosine) 50 mg Capsules at 1-844-483-5636 or medinfo@knighttx.com.

Adverse events, medication errors or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

This letter is not intended as a complete description of the benefits and risks related to the use of Impavido. Please refer to the enclosed full prescribing information and medication guide.

Sincerely,

Arvind Utchanah

p/Knight Therapeutics (USA) Inc.

Arvind Utchanah — President of the board of directors