

June 21, 2017

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IMPORTANT SAFETY INFORMATION:

Availability of Pantoprazole Sodium for Injection, 40 mg
NDC 55150-202-10

Dear Healthcare Professional:

The purpose of this letter is to inform you of efforts to avoid a drug shortage for Pantoprazole Sodium for Injection, a proton pump inhibitor used to block the production of acid by the stomach. In coordination with the U.S. Food and Drug Administration (FDA), AuroMedics Pharma will be distributing Pantoprazole Sodium for Injection manufactured by Aurobindo Pharma Ltd. utilizing an additional packaging line and lyophilization equipment not yet approved by the FDA. AuroMedics Pharma LLC is the U.S. generic injectables subsidiary of Aurobindo Pharma Ltd., and distributes Aurobindo Pharma's injectable drug products in the U.S.

Pantoprazole Sodium for Injection manufactured by Aurobindo Pharma Ltd. from the unapproved packaging line and lyophilization equipment will be traceable by lot number maintained on file at the manufacturing site. The product is acceptable from the pharmaceutical quality standpoint.

Healthcare professionals may order AuroMedics Pantoprazole Sodium for Injection from wholesalers including AmerisourceBergen (item no. 10164054), Cardinal (item no. 5238225), McKesson (item no. 3542982), or Morris & Dickson (item no. 550822). For customer service inquiries, please call AuroMedics Customer Service at 1-888-238-7880 (option 1) or email auromedicscs@aurobindousa.com.

To report adverse events or quality problems experienced with the use of this product, please call AuroMedics Pharma LLC Pharmacovigilance and Medical Affairs at 1-888-238-7880 (option 2) or e-mail pvg@aurobindousa.com.

Adverse events 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, or 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.

For complete prescribing information for AuroMedics Pharma Pantoprazole Sodium for Injection, 40 mg, please visit our website at <http://auromedics.com/> or click on the link below:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9bed093a-9586-4c82-a2b7-c68f89d0faef>

IMPORTANT SAFETY INFORMATION:

Additional Supply of AuroMedics Pharma Pantoprazole Sodium for Injection, 40 mg
NDC 55150-202-10

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Sincerely,
AuroMedics Pharma LLC

Vincent P. Andolina,
Vice-President,
Regulatory Affairs
