SANDOZ A Novartis Division

Sandoz Inc.
100 College Road West
Princeton, NJ 08540 USA
www.us.sandoz.com

Important Correction of Drug Information

March 22, 2019

Notice to Healthcare Professional Regarding Sandoz's Bivalirudin for Injection, 250mg/vial

Dear Healthcare Professional:

The purpose of this letter is to inform you of an issue with respect to an error in the package leaflet which was utilized in lots of Bivalirudin Injection for injection, 250 mg/vial (NDC 0781-3158) packaged between November 2015 and July 2016. Bivalirudin is a direct thrombin inhibitor indicated for use as an anticoagulant.

Summary of an Error

Sandoz's Bivalirudin Injection, 250mg/vial has been identified as having certain lots on the market within expiry that contain a previously identified typographical error. This typographical error is located in the dosing table (Table 1) in the package leaflet. For the low rate infusion, 0.2 mg/kg per hour, the table header incorrectly indicates "Using **5** mg/mL Concentration" instead of "Using **0.5** mg/mL Concentration." This error was corrected in July 2016 and the revised package leaflet was utilized for all subsequent packs. Additionally, all packs within inventory at The Medicines Company and Sandoz in July 2016 were re-worked with new correct leaflets. The online leaflet was also immediately updated in the Daily Med website and available as of July 2016. A Field Alert Report was submitted to FDA relating to this issue in July 2016 by The Medicines Company (previous market authorization holder).

The table below summarizes the lots with package leaflets impacted by this error.

Material Description	Lot	Expiration Date	NDC Code
BIVALIRUDIN 250MG 10LYVI US	00128	31.03.2019	00781315895
BIVALIRUDIN 250MG 10LYVI US	00129	31.03.2019	00781315895
BIVALIRUDIN NOV 250MG 10LYVI V1 US (Novaplus label)	00129	31.03.2019	00781915895
BIVALIRUDIN 250MG 10LYVI US	00132	30.06.2019	00781315895
BIVALIRUDIN 250MG 10LYVI US	00133	31.07.2019	00781315895

Apart from the error in the dosing table in the package leaflet, the product meets all quality attributes and is safe for patient use.

If you have any questions or comments on the information provided in this letter, please contact: Sandoz Quality Compliance Call Center at 1-800-525-2492, Email: qa.drugsafety@sandoz.com.

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Reporting Adverse Events

Healthcare providers should report product quality problems and all suspected adverse events associated with the use of bivalirudin to Sandoz at 1-800-525-2942.

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.

Thank you again for your support.

Sincerely,
SANDOZ INC.

Anthony Maffia III,
Vice President, Regulatory Affairs