IMPORTANT DRUG INFORMATION

November 24th, 2020

Subject: Ampule label barcode readability issue regarding ProvayBlue® (methylene blue) injection USP 50 mg/10 mL

Dear Healthcare Provider,

The purpose of this letter is to inform you of a barcode scanning readability issue reported by some hospitals relating to the ProvayBlue® ampule label.

Barcode Readability Issue

Through investigation of the issue, we determined that changes made to the barcode format on the ampule label renders the barcode unreadable and may display incorrect information by some hospital inventory systems. The barcode change affects only the ampule label; the barcode on the drug product box remains unaffected.

We would like to assure you that the affected barcodes display the correct barcode number: 10305170374010. Also, all other drug product information on the ampule label remains correct.

Remedial Actions

The barcode may not register accurately on the U.S. scanning systems. Institutions should manually input the product into their systems to confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

We are correcting the issue by reverting to the previous barcode format; however, it will take some time for new batches to enter the market.

Lot numbers impacted are:

F8041F03 - F8042F01 - F8043F01 - F8043F03 - F8044F01- F8044F02- F8045F01- F8046F01- F8047F01 -F8048F01 -F8049F01 - F8050F01

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The corrected ProvayBlue® ampule label barcode will be as follows:

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events in patients taking ProvayBlue® to pv@americanregent.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).

We apologize for any inconvenience this may cause as we work diligently to correct the issue.

Sincerely yours,

Muriel Demaegdt
Quality Director

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