Sodium Phosphates Injection: Osmolarity Labeling Correction

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To the Editor:

The labeling for some brands of Sodium Phosphates Injection, United States Pharmacopeia (USP), will be corrected soon to reflect a calculated osmolarity of 7 mOsm/mL instead of the labeled 12 mOsm/mL. Pharmacists who calculate osmolarity for compounded intravenous products should note the change and confirm that any chart/calculator they use to calculate osmolarity is correct.

The error in labeling was noticed during a talk I was giving to my residents on how to calculate the osmolarity of an intravenous product, and how the osmolarity of commercially available additives was determined. Osmolarity of additives is typically measured in mOsm/mL. I explained that Sodium Phosphates Injection contains 3 mmol of phosphate per milliliter and 4 mEq of sodium per milliliter. For additives measured in mmol, it is a simple conversion as 1 mmol equals 1 mOsmol. For additives measured in mEq, it can be more complicated, but for those additives with a valence of ± 1 , such as Na^+ , it is also a simple one-to-one conversion where 1 mEq of Na^+ equals 1 mOsmol of Na^+ .¹ Therefore, the calculated osmolarity of Sodium Phosphates Injection would be 3 + 4 equals 7 mOsmol/mL. There may be some additional NaOH or phosphoric acid added to the solution, but the amount would be slight and not expected to contribute much to the osmolarity of the solution. At this point, one of the residents pointed out that the label on the vial, which was from APP Fresenius Kabi, stated the osmolarity as 12 mOsm/mL.² I found this same information in the *Handbook on Injectable Drugs*³ and at least 1 online osmolarity calculator.⁴

I contacted APP Fresenius Kabi about the discrepancy and was referred to Hospira (now part of Pfizer) who created the original Reference Listed Drug. After some investigation, Pfizer got back to me and informed me that the labeling was indeed incorrect and that they would be changing it from 12 to 7 mOsm/mL (P. Parmar, RPh, personal communication, May 18, 2017). It will take a little time for that change to go into effect, but osmolarity calculations should be corrected now. Of note, the product from American Regent is labeled correctly at 7 mOsm/mL.⁵

References

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