

Extended Use of Alfaxalone After Vial Puncture

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In the Literature

Whitehead MC, Vanetten CL, Jacob ME, Harrison TM. Microbial integrity of preservative-free alfaxalone in a multiple-use system for two storage conditions and three handling techniques. *Am J Vet Res.* 2018;79(7):704-710.

FROM THE PAGE ...

The United States Food and Drug Administration (FDA) mandates that preservative-free alfaxalone be discarded within 6 hours of vial puncture. Preservatives are commonly added to drugs to prevent bacterial contamination, which can occur when a needle punctures the vial stopper. Microbial contamination of drug vials has been identified in human cases of nosocomial morbidity and mortality.¹ The FDA mandate is designed to preserve drug integrity and support patient safety, as the greatest risk for contamination occurs in multidose vials without preservatives, but failure to use the entire vial within the allotted time can result in drug wastage and increased costs.

Because alfaxalone is approved for use until 7 days after vial puncture in Australia,² this study* evaluated the integrity of preservative-free alfaxalone in a multiuse system. Vials were refrigerated (at 39.2°F [4°C]) or stored at room temperature (71.6°F [22°C]). Samples were drawn by daily needle puncture through the rubber stopper of the vial or by 1 of 2 drug withdrawal systems that allowed a single puncture of the rubber stopper. Samples were incubated in soy broth ± subcultured on blood agar.

Although incidence of bacterial contamination was low, 6 of the 22 samples had bacterial growth. One isolate was identified on day 3 in a vial stored at room temperature from the repeated puncture group. The other 5 bacterial isolates were identified on day 7 or later in both refrigerated and room temperature samples. Four of the 6 isolates were from the repeated puncture group.

... TO YOUR PATIENTS

Key pearls to put into practice:

- 1** It is possible to use preservative-free alfaxalone for up to 7 days, with the precaution of using specialized withdrawal equipment that allows only one puncture of the vial's rubber stopper.
- 2** Use of an open vial for more than 7 days is not recommended, especially if the vial has multiple punctures. Although the study authors recommended drug refrigeration, the results do not support refrigeration as a means to decrease contamination.
- 3** Use of preservative-free alfaxalone more than 6 hours after vial puncture should be weighed against patient safety and standard of care. Appropriate patient care could be questioned if nosocomial infection is suspected following alfaxalone administration and the FDA's 6-hour discard requirement has not been followed. Thus, the safest and most defensible option for clinicians is to use alfaxalone with a preservative, which was approved by the FDA in June 2018 and can be used up to 28 days after vial puncture.³

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References

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