

FDA Drug Safety Communication: FDA cautions about dose confusion and medication error with antibacterial drug Avycaz (ceftazidime and avibactam)**Safety Announcement**

[09-22-2015] The U.S. Food and Drug Administration (FDA) is warning health care professionals about the risk for dosing errors with the intravenous antibacterial drug Avycaz (ceftazidime and avibactam) due to confusion about the drug strength displayed on the vial and carton labels. Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (i.e., 2 gram/0.5 gram); however, the product is dosed based on the sum of the active ingredients (i.e., 2.5 gram). To prevent medication errors, we have revised the labels to indicate that each vial contains Avycaz 2.5 gram, equivalent to ceftazidime 2 gram and avibactam 0.5 gram (see Photos).

Avycaz is approved for intravenous administration to treat complicated infections in the urinary tract, or in combination with the antibacterial drug metronidazole to treat complicated infections in the abdomen in patients with limited or no alternative treatment options. Antibacterial drugs work by killing or stopping the growth of bacteria that can cause illness.

Since Avycaz's approval in February 2015, we have received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase antibacterial drugs. Based on the information provided in the reports, we are aware that at least one of the patients received a higher-than-intended dose of Avycaz. No adverse events were reported.

We urge health care professionals and patients to report side effects and medication errors involving Avycaz to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Facts about Avycaz (ceftazidime and avibactam)

- Avycaz is a combination product consisting of ceftazidime, a cephalosporin antibacterial drug, and avibactam, an inhibitor of certain beta-lactamase enzymes.
- Avycaz is approved for intravenous administration to treat complicated urinary tract infections, and to treat complicated intra-abdominal infections in combination with metronidazole in patients with limited or no alternative treatment options.
- Each vial contains 2.5 gram of Avycaz (ceftazidime 2 gram and avibactam 0.5 gram).

Additional Information for Health Care Professionals

- Due to reports of medication errors associated with Avycaz, the vial and carton labels have been revised to indicate that each vial contains Avycaz 2.5 gram, equivalent to ceftazidime 2 gram and avibactam 0.5 gram.
- Avycaz is approved to treat complicated urinary tract infections, including pyelonephritis, and in combination with metronidazole to treat complicated intra-abdominal infections caused by susceptible bacterial pathogens in patients with limited or no alternative treatment options.
- In order to reduce the development of drug-resistant bacteria and maintain antibacterial effectiveness, Avycaz should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.
- The dose of Avycaz must be lowered in patients with renal impairment. The usual dose for normal renal function is 2.5 gram intravenously (over 2 hours) every 8 hours.
- Report adverse reactions and medication errors involving Avycaz to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Data Summary

Since Avycaz’s approval in February 2015, we have received reports of three medication error cases related to how the drug strength was displayed on the Avycaz vial and carton labels (2 gram/0.5 gram per vial).

In two of the three cases, the patients were prescribed 1.25 gram, the recommended dose for their level of renal impairment. The pharmacies prepared the Avycaz dose based on the ceftazidime portion alone rather than the intended 1 gram of ceftazidime and 250 mg of avibactam. No adverse events were reported, but based on the information provided in the postmarketing reports, we are aware that at least one of the two patients received a higher-than-intended dose. The third case described a concern that the strength displayed for Avycaz differed from how drug strengths are displayed for other beta-lactam/beta-lactamase drugs such as Zosyn and Unasyn.

Our evaluation determined that previously approved beta-lactam/beta-lactamase antibacterial drug products express the strength as the sum of the two active ingredients in the labels (e.g., 1.5 gram or 3 gram of ampicillin/sulbactam). Therefore, pharmacists and prescribers are familiar with this convention for expressing the strength of beta-lactam/beta-lactamase antibacterial drugs as the sum of the two active ingredients. Confusion arose when the vial and carton labels of Avycaz expressed the strength to reflect the individual active ingredients.

Photos

Before

Rx only
NDC 0436-2700-01

Avycaz™

(ceftazidime-avibactam)
2 g/0.5 g per vial for injection

Must be constituted then diluted.
For Intravenous Infusion.
Single-use vial - Discard after use

Prior to Constitution: Store at 25°C (77°F). Protect from light.

After Constitution: Use within 12 hrs at room temperature or refrigerate for up to 24 hrs and use within 12 hrs of subsequent change at room temperature. See prescribing information for complete directions for use.

Manufacturer:
Daiichi Sankyo Pharmaceuticals, S.A.
Weymouth, MA 01978
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10000000132776

N0030456370010

After

Rx only
NDC 0436-2700-01

Avycaz™

2.5 g per vial*
(ceftazidime and avibactam) for injection

***Ceftazidime 2 gram (equivalent to 2.835 g ceftazidime pentahydrate/sodium carbonate) and avibactam 0.5 g (equivalent to 0.551 g avibactam sodium).**

For Intravenous Infusion - Single-dose vial - Discard unused portion

MAKET-NE-CON STRIATED-THIN 0.4 L UNIDIS
Store at 25°C (77°F). Protect from light when in carton. See prescribing information for complete directions for use.

Manufacturer:
Daiichi Sankyo Pharmaceuticals, S.A.
Weymouth, MA 01978
1000000000 100-000000

Lot _____
Mfd _____
Exp _____

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