

September 17, 2010

## Valcyte (valganciclovir hydrochloride) Label Change: Possible overdose in pediatric patients



**AUDIENCE:** Transplantation, Infectious Disease, Pediatrics, Pharmacy

**ISSUE:** The FDA is notifying healthcare professionals of new pediatric dosing recommendations for Valcyte (valganciclovir hydrochloride) oral tablets and oral solution. The FDA has determined that adding an upper limit of 150 mL/min/1.73 m<sup>2</sup> to the creatinine clearance calculated using the Schwartz formula for the determination of pediatric doses can help prevent the potential for Valcyte overdosing in children with low body weight, low body surface area, and below normal serum creatinine.

**BACKGROUND:** Valganciclovir is an antiviral medication that can be effective for the prevention of cytomegalovirus (CMV) disease in children 4 months to 16 years of age who have undergone a kidney or heart transplant. Cytomegalovirus is a member of a group of herpes-type viruses that can cause disease in different parts of the body.

**RECOMMENDATION:** If the calculated pediatric dose of Valcyte exceeds 900 mg, a dose of 900 mg should be administered to the child. The dosing calculation can be found in the Drug Safety Communication located on the FDA website (<http://www.fda.gov/Drugs/DrugSafety/ucm225727.htm>). Be aware of possible valganciclovir overdose in pediatric patients with low body weight, low body surface area, or below normal serum creatinine. Report adverse events involving Valcyte to MedWatch:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Download the form from the FDA website 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.

Read the complete MedWatch 2010 Safety summary, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm225888.htm>

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