Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

July 2021

Subject: New Oral Dosing Dispenser with the Use of VALCYTE® (valganciclovir) Oral Solution in Pediatric Patients

Dear Health Care Provider:

Genentech, a Member of the Roche Group, would like to inform you of important information regarding the use of VALCYTE in pediatric patients.

VALCYTE (valganciclovir) for Oral Solution is a deoxynucleoside analogue cytomegalovirus (CMV) DNA polymerase inhibitor approved by the U.S. Food and Drug Administration for use in pediatric patients for prevention of CMV disease in kidney and in heart transplant at high risk.

The purpose of this letter is to inform prescribers that as of July 2021 VALCYTE for Oral Solution will have a new oral dosing dispenser with a change in graduations to administer to pediatric patients. Please refer to the *Recommended Dosage in Pediatric Patients* section of the enclosed full Prescribing Information and Instructions for Use for further details.

These important new additions to the VALCYTE prescribing information are:

Dosing and Administration
The new oral dosing dispenser is provided with a change in graduations to measure and administer the VALCYTE dose. Previously, the dispenser had graduations in increments of 0.2 mL (10 mg). It is recommended to use the new dispenser, which now has graduations in 0.5 mL (25 mg) increments up to 10 mL (500 mg).

The pediatric dosage of VALCYTE is calculated using a modified Schwartz formula. Based upon this calculation, doses must be rounded to the nearest 25 mg increment for the actual deliverable dose. A change in dose for current patients may be warranted.

The following table gives examples of the conversion from mg to mL.

Valganciclovir dose	VALCYTE® for Oral Solution to be administered with the oral dosing dispenser
50 mg	1 mL
75 mg	1.5 mL
100 mg	2 mL
500 mg	10 mL

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Prescriber Action
Counsel patients about the new oral dosing dispenser with a change in graduations to measure and administer the VALCYTE dose.

Reporting Adverse Events
Health Care Providers should report any medication errors and/or adverse events suspected to be associated with the use of VALCYTE to Genentech at 1-888-835-2555 and 1-800-334-0290 respectively.

Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program).

Company Contact Point
You may also contact our medical information department at 1-800-821-8590 if you have any questions about the information contained in this letter or the safe and effective use of VALCYTE.

This letter is not intended as a complete description of the benefits and risks related to the use of VALCYTE. Please refer to the enclosed full Prescribing Information (and Patient Information and Instructions for Use).

Sincerely,

Jamie Freedman

Jamie Freedman MD, PhD
Head of U.S. Medical Affairs