

Instructions for Use
Valganciclovir (val[®] gan[®] sye[®] kloe[®] vir)
for Oral Solution

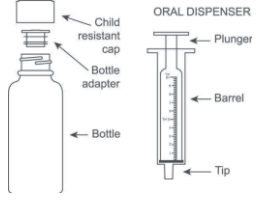
Be sure that you read, and that you understand and follow these instructions carefully to ensure proper dosing of the oral solution.

Important:

- Avoid contact with your skin or eyes. If you come in contact with the contents of the oral solution, wash your skin well with soap and water or rinse your eyes well with plain water.
- Do not use valganciclovir for oral solution after the discard date on the bottle.
- Always use the oral dispenser provided to give or take a dose of valganciclovir for oral solution.
- Call your pharmacist if your oral dispenser is lost or damaged, and they will tell you how to continue to give or take a dose of valganciclovir for oral solution.
- Ask your healthcare provider or pharmacist to show you how to measure your prescribed dose.

To take a dose of valganciclovir for oral solution, you will need the bottle of medicine and an oral dispenser provided with the medicine (see Figure 1). Your pharmacist inserts the bottle adapter in the valganciclovir for oral solution bottle.

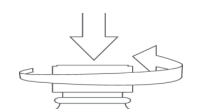
FIGURE 1



Step 1: With the child-resistant cap on the bottle, shake the bottle well for about 5 seconds before each use.



Step 2: Open the bottle by pressing downward firmly on the child-resistant cap and turning it counter-clockwise. Do not throw away the child-resistant cap.



Step 3: Check the dose in milliliters (mL) as prescribed by your healthcare provider. Find this number on the oral dispenser.



Step 4: Push the plunger down toward the tip of the oral dispenser.



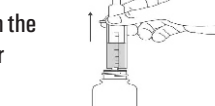
Step 5: With the bottle in an upright position, insert the oral dispenser into the bottle adapter opening until firmly in place.



Step 6: Carefully turn the bottle upside down with the oral dispenser in place. Pull the plunger to withdraw the prescribed dose. If you see air bubbles in the oral dispenser, fully push in the plunger so that the oral solution flows back into the bottle. Then withdraw your prescribed dose of valganciclovir for oral solution.



Step 7: Leave the oral dispenser in the bottle adapter and turn the bottle to an upright position. Slowly remove the oral dispenser from the bottle adapter.



Step 8: Give or take the dose of valganciclovir for oral solution. Place the tip of the oral dispenser in the mouth. Slowly push down the oral dispenser plunger until the oral dispenser is empty.

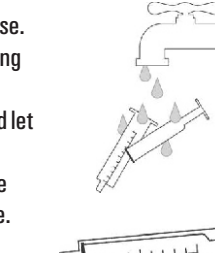


Step 9: Put the child-resistant cap back on the bottle. Return the bottle back to the refrigerator.



Step 10: Rinse the oral dispenser with tap water after each use.

- Remove the plunger from the oral dispenser barrel by pulling the plunger all the way out of the barrel.
- Rinse the oral dispenser barrel and plunger with water and let them air dry.
- When the oral dispenser barrel and plunger are dry, put the plunger back into the oral dispenser barrel for the next use.



How should I store valganciclovir for oral solution?

- Store solution in the refrigerator at 36°F to 46°F (2°C to 8°C) for no longer than 49 days.
- Do not freeze.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

For more information, call Annona Pharma Private Limited at 1-866-495-1995.

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Revised: 09/2022

*Data were obtained from single and multiple dose studies in healthy volunteers, HIV positive patients, and HIV positive CMV positive patients with and without retinitis. Patients with CMV retinitis tended to have higher ganciclovir plasma concentrations than patients without CMV retinitis.

The systemic ganciclovir exposure attained following administration of 900 mg valganciclovir tablets once daily were comparable across kidney, heart and liver transplant recipients (Table 11).

Table 11 Ganciclovir Pharmacokinetics in Solid Organ Transplant Recipients Administered Valganciclovir Tablets 900 mg Once Daily with Food

Parameter	Heart Transplant Recipients (N=17)	Value (Mean ± SD) Liver Transplant Recipients (N=79)	Kidney Transplant Recipients (N=68)
AUC _{0-24h} (mg·h/mL)	40.2 ± 11.8	46.0 ± 16.1	48.2 ± 14.8
C _{max} (mg/mL)	2.8 ± 0.9	3.1 ± 1.0	3.2 ± 1.0
Elimination half-life (hr)	6.58 ± 1.50	6.18 ± 1.42	6.77 ± 1.25

Includes kidney processes
The pharmacokinetic parameters of ganciclovir following 200 days of valganciclovir administration in high-risk kidney transplant patients were similar to those in solid organ transplant patients who received valganciclovir for 100 days.

Absorption, Distribution, Metabolism, and Excretion
The pharmacokinetic PKI properties of ganciclovir are provided in Table 12.

Table 12 Pharmacokinetic Properties of Ganciclovir and Valganciclovir Associated with Valganciclovir Tablets

Parameter	Valganciclovir	Ganciclovir
Absorption		
T _{max} (h) (median interval) (fed condition)	2.18	1.76 to 3.50
Food effect (high fat meal/feeding): PK parameter ratio and 95% confidence interval*	1.14 (0.95, 1.36)	4.93 ± 1.4
AUC _{0-24h} (mg·h/mL)	AUC _{0-24h} 1.30 (1.07, 1.51) T _{max} 2.18	
Distribution		
% Bound to human plasma proteins (in vivo)	Unknown	1 to 2% over 0.5 to 61 mg/mL
Central/skin fluid penetration	Unknown	Yes
Metabolism	Hydrolyzed by intestinal and liver esterases	No significant metabolism
Elimination		
Dose proportionality		AUC was dose proportional under fed conditions across a valganciclovir dose range of 40 to 2025 mg
Major route of elimination (t _{1/2})	Metabolism to ganciclovir	Elimination by renal and active tubular secretion (t _{1/2})
% of dose excreted in urine	Unknown	Unknown
% of dose excreted in feces	Unknown	Unknown

Steady state ganciclovir PK was assessed after administration of valganciclovir tablets (875 mg once daily) with a high fat meal containing approximately 500 kcal (S1, 1 to 4), S1: S2: S3: S4: S5: S6: S7: S8: S9: S10: S11: S12: S13: S14: S15: S16: S17: S18: S19: S20: S21: S22: S23: S24: S25: S26: S27: S28: S29: S30: S31: S32: S33: S34: S35: S36: S37: S38: S39: S40: S41: S42: S43: S44: S45: S46: S47: S48: S49: S50: S51: S52: S53: S54: S55: S56: S57: S58: S59: S60: S61: S62: S63: S64: S65: S66: S67: S68: S69: S70: S71: S72: S73: S74: S75: S76: S77: S78: S79: S80: S81: S82: S83: S84: S85: S86: S87: S88: S89: S90: S91: S92: S93: S94: S95: S96: S97: S98: S99: S100: S101: S102: S103: S104: S105: S106: S107: S108: S109: S110: S111: S112: S113: S114: S115: S116: S117: S118: S119: S120: S121: S122: S123: S124: S125: S126: S127: S128: S129: S130: S131: S132: S133: S134: S135: S136: S137: S138: S139: S140: S141: S142: S143: S144: S145: S146: S147: S148: S149: S150: S151: S152: S153: S154: S155: 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