Valganciclovir For Oral Solution 50 mg /ml Powder

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	**INDICATIONS AND USAGE** Valganciclovir is a deoxynucleoside analogue cytomegalovirus (CMV) DNA polymerase inhibitor indicated for: **Adult Patients** Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS). Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk. **Pediatric Patients** Prevention of CMV disease in kidney and heart transplant patients at high risk.
2.	Dosage	What is the recommended dosage?	**Adult Dosage:** **Treatment of CMV retinitis:** Induction: 900 mg (two 450 mg tablets) twice a day for 21 days Maintenance: 900 mg (two 450 mg tablets) once a day **Prevention of CMV disease in heart or kidney-pancreas transplant patients**: 900 mg (two 450 mg tablets) once a day within 10days of transplantation until 100 days' post-transplantation **Prevention of CMV disease in kidney transplant patients:** 900 mg (two 450 mg tablets) once a day within 10days of transplantation until 200 days' post-transplantation **Pediatric Dosage:** **Prevention of CMV disease in kidney transplant patients 4months to 16 years of age:** Dose once a day within 10 days of transplantation until 200 days' post transplantation according to dosage algorithm (note the calculation of creatinine clearance using a modified Schwartz formula in children). **Prevention of CMV disease in heart transplant patients 1month to 16 years of age:** Dose once a day within 10 days of transplantation until 100 days post transplantation according to dosage algorithm (note the calculation of creatinine clearance using a modified Schwartz formula in children)

3.	Administration	How do I take?	Adult patients should use valganciclovir tablets, not valganciclovir for oral solution. Valganciclovir for oral solution and tablets should be taken with food. Valganciclovir for oral solution (50 mg/mL) must be prepared by the pharmacist prior to dispensing to the patient. **Please refer Patient information for more details**
4.	Side effects	What are the most common and possible side effects?	**Most common side effects in adults for valganciclovir for oral solution: diarrhea** low white cell, red cell and platelet cell counts in blood tests, fever, headache, fatigue, sleeplessness, nausea, urinary tract infection, shaky movements (tremors), vomiting **Most common side effects in Children for valganciclovir for oral solution:** Diarrhea, vomiting, fever, low white blood cell counts in blood tests, upper respiratory tract infection, headache, urinary tract infection.
5.	Administration	Use in Pediatric Population	Valganciclovir for oral solution and tablets are indicated for the prevention of CMV disease in pediatric kidney transplant patients 4 months to 16 years of age and in pediatric heart transplant patients 1 month to 16 years of age at risk for developing CMV Disease. The use of Val ganciclovir for oral solution and tablets for the prevention of CMV disease in pediatric kidney transplant patients 4 months to 16 years of age is based on two single arm, open label, non-comparative studies in patients 4 months to 16 years of age. A pharmacokinetic and pharmacodynamics evaluation of valganciclovir for oral solution was performed in 24 neonates with congenital CMV infection involving the central nervous system. All patients were treated for 6 weeks with a combination of intravenous ganciclovir 6 mg per kg twice daily or valganciclovir for oral solution at doses ranging from 14 mg per kg to 20 mg per kg twice daily. The pharmacokinetic results showed that in infants greater than 7 days to 3 months of age, a dose of 16 mg per kg twice daily of valganciclovir for oral solution provided ganciclovir systemic exposures (median AUC0-12h = 23.6 [range 16.8 to 35.5] mcg·h/mL; n = 6) comparable to those obtained in infants up to 3 months of age from a 6 mg per kg dose of intravenous ganciclovir twice daily (AUC = 25.3 [range 2.4 to 89.7] mcg·h/mL; n = 18) or to the ganciclovir systemic exposures obtained in adults from a 900 mg dose of valganciclovir tablets twice daily. However, the efficacy and safety of intravenous ganciclovir and of valganciclovir have not been established for the treatment of congenital CMV infection in infants and no similar disease occurs in adults; therefore, efficacy cannot be extrapolated from intravenous ganciclovir use in adults.
6.	Administration	Use in Geriatric Population	Studies of valganciclovir for oral solution or tablets have not been conducted in adults older than 65 years of age. Clinical studies of valganciclovir did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing

			range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Valganciclovir is known to be substantially excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because renal clearance decreases with age, valganciclovir should be administered with consideration of their renal status. Renal function should be monitored and dosage adjustments should be made accordingly.
7.	Mechanism	Mechanism of Action	Valganciclovir is an antiviral drug with activity against CMV Valganciclovir is an L-valyl ester (prodrug) of ganciclovir that exists as a mixture of two diastereomers. After oral administration, both diastereomers are rapidly converted to ganciclovir by intestinal and hepatic esterase's. Ganciclovir is a synthetic analogue of 2' deoxyguanosine, which inhibits replication of human CMV in cell culture and in vivo. In CMV-infected cells, ganciclovir is initially phosphorylated to ganciclovir monophosphate by the viral protein kinase, pUL97. Further phosphorylation occurs by cellular kinases to produce ganciclovir triphosphate, which is then slowly metabolized intracellularly (half-life 18 hours). As the phosphorylation is largely dependent on the viral kinase, phosphorylation of ganciclovir occurs preferentially in virus-infected cells. The virustatic activity of ganciclovir is due to inhibition of the viral DNA polymerase, pUL54 by ganciclovir triphosphate.
8.	Warning	Warnings and precautions	Acute renal failure: Acute renal failure may occur in elderly patients (with or without reduced renal function), patients who receive concomitant nephrotoxic drugs, or inadequately hydrated patients. Use with caution in elderly patients or those taking nephrotoxic drugs, reduce dosage in patients with renal impairment, and monitor renal function.
9.	Lactation	Use in Lactation	Breastfeeding is not recommended with use of valganciclovir.
10.	Pregnancy	Use in Pregnancy	Data from an ex-vivo human placental model showed that ganciclovir crosses the human placenta. The transfer occurred by passive diffusion and was not saturable over a concentration range of 1 to 10 mg/mL **Please refer Patient information for more details**
11.	Storage	What are the storage conditions?	Store dry powder at 20°C to 25°C (68°F to 77°F); excursions are permitted to 15°C tom30°C (59°F to 86°F) [see USP controlled room temperature]. Store constituted solution under refrigeration at 2°C to 8°C (36°F to 46°F) for no longer than 49 days. Do not freeze.
12.	Dispensing	How to Dispense?	As prescribed by the Physician
13.	Contraindication	What are the contraindications of (medication)?	Hypersensitivity to valganciclovir or ganciclovir.
Pharmaceutical Particulars			

14.	Pharmaceutical Form	How Supplied	Valganciclovir for oral solution: Supplied as a white to slightly yellow powder blend for constitution, forming a colorless to brownish-yellow tutti-frutti flavored solution. Available in glass bottles containing approximately 100 mL of solution after constitution. Each bottle can deliver up to a total of 88 mL of solution. Each bottle is supplied with a bottle adapter and 2 oral dispensers (NDC 72205-019-01). Prior to dispensing to the patient, valganciclovir for oral solution must be prepared by the pharmacist.
15.	Ingredients	Active and Inactive	**Active ingredient:** valganciclovir hydrochloride, USP **Inactive ingredients**: fumaric acid, mannitol, povidone K-29/32, saccharin sodium, sodium benzoate, and tutti-frutti flavoring.
Allergens			
16.	Ingredients	Does it contain Gluten?	No
17.	Ingredients	Does it contain alcohol?	No
18.	Ingredients	Does it contain dyes?	No
19.	Ingredients	Does it contain Lactose?	No
20.	Ingredients	Does it contain Nuts?	No
21.	Ingredients	Does it contain Preservatives?	No
22.	Ingredients	Does it contain Soy products?	No
23.	Ingredients	Does it contain peanut?	No
24.	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
Miscellaneous			
25.	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products
26.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
27.	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company
28.	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products

		medicine, no longer fills my prescription with Novadoz formulation?	
29.	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN pharmaceuticals Inc. Piscataway, NJ 08854. **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714 TEL: 855-NOVADOZ (668-2369)