Valganciclovir for oral solution 50mg/ml

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	**Valganciclovir oral solution is indicated in** **1.1 Adult Patients** • **Treatment of CMV Retinitis**: Indicated for patients with AIDS. • **Prevention of CMV Disease**: Indicated for high-risk kidney, heart, and kidney-pancreas transplant patients (D+/R-). **1.2 Paediatric Patients** • **Prevention of CMV Disease**: Indicated for high-risk kidney transplant patients (4 months to 16 years) and heart transplant patients (1 month to 16 years).
2	Dosage	What is the recommended dosage?	**Recommended Dosage in Adult Patients with Normal Renal Function** **CMV Retinitis:** • **Induction**: 900 mg (two 450 mg tablets) orally twice daily for 21 days. • **Maintenance**: 900 mg (two 450 mg tablets) orally once daily for inactive CMV retinitis. **Prevention of CMV Disease:** • **Heart/Kidney-Pancreas Transplant**: 900 mg orally once daily for 100 days post-transplant (starting within 10 days). • **Kidney Transplant**: 900 mg orally once daily for 200 days post-transplant (starting within 10 days). **Recommended Dosage in Pediatric Patients**

			Prevention of CMV Disease:
			
			• **Kidney Transplant (4 months to 16 years)**: Dose calculated as 7×BSA×CrCl7 \times \text {BSA} \times \text {CrCl}7×BSA×CrCl starting within 10 days until 200 days post-transplant.
			• **Heart Transplant (1 month to 16 years)**: Same formula, until 100 days post-transplant.
			
			Calculation Details:
			
			• Use the modified Schwartz formula for CrCl; maximum value of 150 mL/min/1.73m² if exceeded.
			• **k Values** (based on age):
			  ○ <1 year (low birth weight): 0.33
			  ○ <1 year (normal weight): 0.45
			  ○ 1 to <2 years: 0.45
			  ○ 2 to <13 years: 0.55
			  ○ 13 to 16 years (boys): 0.7

3	Administration	How do I take it?	Valganciclovir for oral solution and tablets should be taken with food.
4	Formulation	Can tablet be crushed?	No
5	Administration	What do I do if I miss a dose?	If you miss a dose Valganciclovir for oral solution continue your prescribed course of therapy, and contact your physician immediately.
6	Administration	Use in Pediatric Population	**Indications for Valganciclovir in Pediatric Patients** **Prevention of CMV Disease:** • **Paediatric Kidney Transplant Patients** (4 months to 16 years): Indicated based on two studies—one focused on safety and pharmacokinetics, and another on safety and tolerability. Valganciclovir is administered once daily starting within 10 days post-transplant for up to 200 days. • **Paediatric Heart Transplant Patients** (1 month to 16 years): Indicated based on the same two studies, along with a pharmacokinetic study in patients under 4 months. However, due to uncertainty in dosing predictions, it is not indicated for patients under 1 month. **Safety and Efficacy Limitations:**

			• Not established for:
			  ○ Pediatric liver transplant patients.
			  ○ Kidney transplant patients under 4 months.
			  ○ Heart transplant patients under 1 month.
			  ○ Pediatric AIDS patients with CMV retinitis.
			  ○ Infants with congenital CMV infection.
			
			Pharmacokinetic Study in Neonates:
			
			• In a study involving neonates with congenital CMV, doses of 16 mg/kg twice daily provided comparable ganciclovir exposure to standard doses of intravenous ganciclovir. However, the efficacy and safety of both ganciclovir and valganciclovir for treating congenital CMV infection in infants remain unestablished.

7	Administration	Use in Geriatric Population	Valganciclovir studies have not included sufficient participants over 65 years to assess differences in response compared to younger adults. Caution is advised when dosing elderly patients, typically starting at the lower end of the range due to increased likelihood of decreased hepatic, renal, or cardiac function and potential drug interactions. Given that valganciclovir is primarily excreted by the kidneys, the risk of toxicity may be higher in those with renal impairment, which can worsen with age. Renal function should be monitored, and dosage adjustments made as necessary.
8	Mechanism	Mechanism of Action	Mechanism of Action of Valganciclovir Valganciclovir is an L-valyl ester (prodrug) of ganciclovir, consisting of two diastereomers. After oral administration, both are quickly converted to ganciclovir by intestinal and hepatic esterases. Ganciclovir, a synthetic analogue of 2' deoxyguanosine, inhibits human CMV replication. In CMV-infected cells, it is first phosphorylated to ganciclovir monophosphate by the viral kinase pUL97, followed by further phosphorylation to ganciclovir triphosphate by cellular kinases. This triphosphate, with an intracellular half-life of 18 hours, selectively inhibits the viral DNA polymerase pUL54, resulting in virustatic activity primarily in virus-infected cells.
9	Warning	Black Box Warning	**WARNING: HEMATOLOGIC TOXICITY, IMPAIRMENT OF FERTILITY, FETAL TOXICITY,**

			MUTAGENESIS AND CARCINOGENESIS **WARNING: HEMATOLOGIC TOXICITY, IMPAIRMENT OF FERTILITY, FETAL TOXICITY, MUTAGENESIS AND CARCINOGENESIS** • **Hematologic Toxicity: Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, and bone marrow failure including aplastic anemia have been reported in patients treated with valganciclovir** • **Impairment of Fertility: Based on animal data and limited human data, valganciclovir may cause temporary or permanent inhibition of spermatogenesis in males and suppression of fertility in females** • **Fetal Toxicity: Based on animal data, valganciclovir has the potential to cause birth defects in humans** • **Mutagenesis and Carcinogenesis: Based on animal data, valganciclovir has the potential to cause cancers in humans**
10	Lactation	Use in Lactation	There is no data on the presence of valganciclovir or ganciclovir in human milk, nor on their effects on breastfed infants or milk production. Animal studies indicate that ganciclovir is excreted in the milk of lactating rats. The CDC recommends that HIV-infected mothers avoid breastfeeding to reduce the risk of postnatal HIV transmission. Therefore, nursing mothers should be advised against breastfeeding during valganciclovir treatment due to potential serious adverse effects on infants and the risk of HIV transmission.
11	Pregnancy	Use in Pregnancy	**Risk Summary:** Valganciclovir, a prodrug converted to ganciclovir, is expected to have similar reproductive toxicity effects. Animal studies show that ganciclovir caused maternal and fetal toxicity, embryo-fetal mortality, and teratogenicity in rabbits at exposures twice that of humans. There are no human data on the use of valganciclovir or ganciclovir in pregnant women to determine drug-associated risks. The background risk for major birth defects is 2-4%, and the risk of miscarriage is 15-20% in the general U.S. population. Pregnant women should be advised of potential risks to the fetus. **Clinical Considerations:** Most maternal CMV infections are asymptomatic, but in immunocompromised patients, they can lead to significant morbidity and mortality. Maternal viremia can transmit CMV to the fetus, with about 10% of infants with congenital CMV being symptomatic at birth. Mortality in these infants is around

			10%, and 50-90% of symptomatic survivors may face serious health issues, including mental retardation and hearing loss. The risk of congenital infection is higher with primary maternal CMV infections compared to reactivation.
12	Precautions	Is there any interaction between medication and alcohol?	None
13	Interaction	Is there any interaction with food?	Take valganciclovir for oral solution with food.
14	Side effects	What are the common side effects?	• 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
15	Storage	What are the storage conditions?	Store valganciclovir for oral solution in the refrigerator between 36°F to 46°F (2°C to 8°C), for no longer than 49 days. • Do not freeze. • Do not keep valganciclovir for oral solution that is out of date or that you no longer need. Keep valganciclovir for oral solution and all medicines out of the reach of children.
16	Dispensing	How to Dispense?	As prescribed by the Physician
17	Contraindication	What are the contraindications of (medication).	Valganciclovir is contraindicated in patients who have experienced a clinically significant hypersensitivity reaction (e.g., anaphylaxis) to valganciclovir, ganciclovir, or any component of the formulation.
Pharmaceutical Particulars			
18	Pharmaceutical Form	How is it 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).
19	Ingredients	Active and Inactive Ingredients	**Active** valganciclovir hydrochloride, USP **Inactive**: fumaric acid, mannitol, povidone K-29/32, saccharin sodium, sodium benzoate, and tutti-frutti flavoring.

20	Coating	What is the type of coating?	None
Allergens			
21	Ingredients	Is it Vegetarian?	yes
22	Ingredients	Does it contain Gluten?	No
23	Ingredients	Does it contain Dairy Products?	No
24	Ingredients	Does it contain Casein	No
25	Ingredients	Does it contain Whey?	No
26	Ingredients	Does it contain corn?	No
27	Ingredients	Does it contain rye?	No
28	Ingredients	Does it contain sugar?	No
29	Ingredients	Does it contain Oats?	No
30	Ingredients	Does it contain wheat?	No
31	Ingredients	Does it contain spelt?	No
32	Ingredients	Does it contain barley?	No
33	Ingredients	Does it contain rennet?	No
34	Ingredients	Does it contain starch?	No
35	Ingredients	Does it contain Iodine?	No
36	Ingredients	Does it contain latex?	No
37	Ingredients	Does it contain alcohol?	No
38	Ingredients	Does it contain dyes?	No
39	Ingredients	Does it contain flavor?	No
40	Ingredients	Does it contain Lactose?	No
41	Ingredients	Does it contain Nuts?	No
42	Ingredients	Does it contain Preservatives?	Yes
43	Ingredients	Does it contain Soy products?	No
44	Ingredients	Does it contain peanut?	No
45	Ingredients	Does it contain nickel?	No

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Miscellaneous	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.
47	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
48	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.
49	Miscellaneous	How do I report an adverse drug effect or reaction to Novadoz medication?	To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
50	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	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.
51	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** **MSN Pharmaceuticals Inc.** **20, Duke Road,** **Piscataway, NJ 08854, USA** **Distributed by:** **Novadoz Pharmaceuticals LLC** **Piscataway, NJ 08854-3714**