NOVADOZ
AN MSN COMPANY

ACYCLOVIR SUSPENSION USP, 200 mg

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	**Herpes Zoster Infections** Acyclovir is indicated for the acute treatment of herpes zoster (shingles). **Genital Herpes** Acyclovir is indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes. **Chickenpox** Acyclovir is indicated for the treatment of chickenpox (varicella).
2.	Dosage	What is the recommended dosage?	The recommended dose of **Acyclovir Suspension is** **For Acute Treatment of Herpes Zoster** 800 mg every 4 hours orally, 5 times daily for 7 to 10 days **For Genital Herpes** ***Treatment of Initial Genital Herpes*** 200 mg every 4 hours, 5 times daily for 10 days ***Chronic Suppressive Therapy for Recurrent Genital Herpes:*** **Standard Dose:** 400 mg twice daily for up to 12 months, with re-evaluation after 1 year. **Alternative Regimens:** 200 mg 3 to 5 times daily. **Intermittent Therapy:** • **Dosage:** 200 mg every 4 hours, 5 times daily for 5 days. • **Initiation:** Start at the earliest sign or symptom of recurrence. **Treatment of Chickenpox:** • **Children (2 years and older):** 20 mg/kg per dose orally, 4 times daily for 5 days (max 80 mg/kg/day). Children over 40 kg receive the adult dose. • **Adults and Children over 40 kg:** 800 mg 4 times daily

			for 5 days. • **Intravenous Acyclovir:** For immunocompromised patients. Start at the earliest sign of chickenpox; efficacy is not established if started more than 24 hours after symptom onset **Patients with Acute or Chronic Renal Impairment:** **Dosage Adjustments Based on Creatinine Clearance:** • **Creatinine Clearance >25 mL/min:** o **Dosage:** 800 mg every 4 hours, 5 times daily. • **Creatinine Clearance 10-25 mL/min:** o **Dosage:** 800 mg every 8 hours. • **Creatinine Clearance 0-10 mL/min:** o **Dosage:** 800 mg every 12 hours. **Alternate Dosages:** • **Creatinine Clearance >10 mL/min:** o **Dosage:** 400 mg every 12 hours. • **Creatinine Clearance 0-10 mL/min:** o **Dosage:** 200 mg every 12 hours.
3.	Administration	How do I take it?	Acyclovir oral suspension may be administered with or without food.
4.	Administration	Use in Pediatric Population	The pharmacokinetics of acyclovir in pediatric patients is similar to that of adults. Mean half-life after oral doses of 300 mg/m2 and 600 mg/m2 in pediatric patients aged 7 months to 7 years was 2.6 hours (range 1.59 to 3.74 hours).
5.	Administration	Use in Geriatric Population	Acyclovir plasma concentrations are higher in geriatric patients compared with younger adults, in part due to age-related changes in renal function. Dosage reduction may be required in geriatric patients with underlying renal impairment
6.	Mechanism	Mechanism of Action	**Mechanism of Antiviral Action:** Acyclovir, a synthetic purine nucleoside analogue, inhibits herpes simplex viruses (HSV-1, HSV-2) and varicella-zoster virus (VZV). It is selectively activated by viral thymidine kinase (TK), converting it to acyclovir monophosphate, then to diphosphate and triphosphate. Acyclovir triphosphate inhibits viral DNA replication by: 1) competitive inhibition of viral DNA polymerase, 2) incorporation into and termination of viral DNA, and 3) inactivation of viral DNA polymerase. Acyclovir is more effective against HSV due to better phosphorylation by viral TK.
7.	Warning	Warnings while using	**Acyclovir Oral Suspension** is for oral use only. Renal failure, potentially fatal, and thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS) have been reported with acyclovir therapy, particularly in immunocompromised patients.
8.	Lactation	Use in Lactation	Patients should consult their physician they intend to breastfeed
9.	Pregnancy	Use in Pregnancy	Patients should consult their physician if they experience severe adverse reactions, become or plan to become pregnant, intend to breastfeed, or have other questions.

10.	Precautions	Precautions while using	**Coadministration of nephrotoxic agents** Caution is needed when administering acyclovir with nephrotoxic agents due to increased risk of renal dysfunction and central nervous system symptoms. Ensure adequate hydration.
11.	Interaction	Is there any interaction with medication?	**Coadministration of probenecid** with intravenous acyclovir increases the mean half-life and area under the concentration-time curve of acyclovir, while reducing urinary excretion and renal clearance.
12.	Storage	What are the storage conditions?	Store at 15° to 25°C (59° to 77°F). Protect from light.
13.	Dispensing	How to Dispense?	As prescribed by the Physician
14.	Contraindication	What are the contraindications of (medication).	Acyclovir is contraindicated for patients who develop hypersensit ivity to acyclovir or valacyclovir.
Pharmaceutical Particulars			
15.	Pharmaceutical Form	How is it supplied?	Acyclovir Oral Suspension, USP contains 200 mg of acyclovir, USP in each teaspoonful (5 mL). The white to off white, banana flavored suspension is available as follows: (NDC 72205-170-72) 1-pint bottle (473 mL)
16.	Ingredients	Active and Inactive Ingredients	**Active** Each teaspoonful (5 mL) of acyclovir oral suspension, USP contains 200 mg of acyclovir **Inactive**: carboxyl methyl cellulose sodium, glycerin, methyl paraben, microcrystalline cellulose, propyl paraben, purified water, sorbitol solution and banana flavor (propylene glycol, Nat & Art flavor).
Allergens			
17.	Ingredients	Is it Vegetarian?	yes
18.	Ingredients	Does it contain Gluten?	No
19.	Ingredients	Does it contain Dairy Products?	No
20.	Ingredients	Does it contain Casein	No
21.	Ingredients	Does it contain Whey?	No
22.	Ingredients	Does it contain corn?	No
23.	Ingredients	Does it contain rye?	No
24.	Ingredients	Does it contain sugar?	No
25.	Ingredients	Does it contain Oats?	No
26.	Ingredients	Does it contain wheat?	No
27.	Ingredients	Does it contain spelt?	No

28.	Ingredients	Does it contain barley?	No
29.	Ingredients	Does it contain rennet?	No
30.	Ingredients	Does it contain starch?	No
31.	Ingredients	Does it contain Iodine?	No
32.	Ingredients	Does it contain latex?	No
33.	Ingredients	Does it contain alcohol?	Yes; Acyclovir API contains Toluene NMT 890 PPM
34.	Ingredients	Does it contain dyes?	No
35.	Ingredients	Does it contain flavor?	Yes; banana flavor
36.	Ingredients	Does it contain Lactose?	No
37.	Ingredients	Does it contain Nuts?	No
38.	Ingredients	Does it contain Preservatives?	Yes; Methylparaben and Propyylparaben
39.	Ingredients	Does it contain Soy products?	No
40.	Ingredients	Does it contain peanut?	No
			Miscellaneous
41.	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
42.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
43.	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.
44.	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.
45.	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.
46.	Miscellaneous	Manufacturer and Distributor	**Manufactured by:** MSN Pharmaceuticals Inc. Piscataway, NJ 08854 **Distributed by:** Novadoz Pharmaceuticals LLC

			Piscataway, NJ 08854-3714