Oseltamivir Phosphate for Oral Suspension 6 mg (base)/mL

S.No.	Category	Question	Answer
Clinical Particulars			
1.	Use/Indication	What is the product indicated for?	**INDICATIONS AND USAGE** Oseltamivir phosphate for oral suspension is an influenza neuraminidase inhibitor (NAI) indicated for: • Treatment of acute, uncomplicated influenza A and B in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours. • Prophylaxis of influenza A and B in patients 1 year and older. Limitations of Use: • Not a substitute for annual influenza vaccination. • Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use. • Not recommended for patients with end-stage renal disease not undergoing dialysis.
2.	Dosage	What is the recommended dosage?	**Treatment of influenza** • Adults and adolescents (13 years and older): 75 mg twice daily for 5 days • Pediatric patients 1 to 12 years of age: Based on weight twice daily for 5 days • Pediatric patients 2 weeks to less than 1 year of age: 3 mg/kg twice daily for 5 days • Renal impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg twice daily for 5 days • Renal impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once daily for 5 days • ESRD patients on hemodialysis: Reduce to 30 mg immediately and then 30 mg after every hemodialysis cycle. Treatment duration not to exceed 5 days • ESRD patients on CAPD: Reduce to a single 30 mg dose immediately **Prophylaxis of influenza** • Adults and adolescents (13 years and older): 75 mg once daily for at least 10 days • Community outbreak: 75 mg once daily for up to 6 weeks. • Pediatric patients 1 to 12 years of age: Based on weight once daily for 10 days • Community outbreak: Based on weight once daily for up to 6weeks. • Renal impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg once daily • Renal impaired adult patients (creatinine clearance >10-30 mL/min): Reduce to 30 mg once every other day

			• ESRD patients on hemodialysis: Reduce to 30 mg immediately and then 30 mg after alternate hemodialysis cycles for the recommended duration of prophylaxis • ESRD patients on CAPD: Reduce to 30 mg immediately and then 30 mg once weekly for the recommended duration of prophylaxis
3.	Administration	How do I take?	The oral suspension may be taken with or without food; however, tolerability may be enhanced if oseltamivir phosphate capsules is taken with food. Adjust the oseltamivir phosphate oral suspension dosage in patients with moderate or severe renal impairment.
4.	Administration	What do I do if I miss a dose?	If you miss a dose of oseltamivir phosphate for oral suspension, take it as soon as you remember. If it is 2 hours or less before your next dose, do not take the missed dose. Take your next dose of oseltamivir phosphate for oral suspension, at your scheduled time. Do not take 2 doses at the same time.
5.	Side effects	What are the most common and possible side effects?	skin rash or hives, swelling of your face, eyes, lips, tongue, or throat, skin blisters and peels, trouble breathing blisters or sores in mouth, chest pain or tightness, itching People, especially children, who have the flu, can develop nervous system problems and abnormal behavior that can lead to death. During treatment with oseltamivir phosphate for oral suspension, tell your healthcare provider right away if you or your child have confusion, speech problems, shaky movements, seizures, or start hearing voices or seeing things that are not really there (hallucinations).
6.	Administration	Use in Pediatric Population	The safety and efficacy of oseltamivir phosphate for prophylaxis of influenza have not been established for pediatric patients less than 1 year of age.
7.	Administration	Use in Geriatric Population	No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger subjects
8.	Mechanism	Mechanism of Action	Oseltamivir is an antiviral drug with activity against influenza virus Oseltamivir phosphate is an ethyl ester prodrug requiring ester hydrolysis for conversion to the active form, oseltamivir carboxylate. Oseltamivir carboxylate is an inhibitor of influenza virus neuraminidase affecting release of viral particles. The median IC values of oseltamivir against influenza A/H1N1, influenza A/H3N2, and influenza B clinical isolates were 2.5 NM (range 0.93 to 4.16 NM, N=74), 0.96 NM (range 0.13 to 7.95 NM, N=774), and 60 NM (20 to 285 NM, N=256), respectively, in a neuraminidase assay with a fluorescently labeled MUNANA substrate.

9.	Warning	Warnings and precautions	Serious skin/hypersensitivity reactions such as Stevens-Johnson Syndrome, toxic epidermal necrolysis and erythema multiform: Discontinue oseltamivir phosphate and initiate appropriate treatment if allergic-like reactions occur or are suspected. Neuropsychiatric events: Patients with influenza, including those receiving oseltamivir phosphate particularly pediatric patients, may be at an increased risk of confusion or abnormal behavior early in particularly pediatric patients, may be at an increased risk of confusion or abnormal behavior early in their illness. Monitor for signs of abnormal behavior.
10.	Lactation	Use in Lactation	Based on limited published data, oseltamivir and oseltamivir carboxylate have been shown to be present in human milk at low levels considered unlikely to lead to toxicity in the breastfed infant. Post marketing experience has not reported any information to suggest serious adverse effects of oseltamivir exposure via breast milk in infants. It is not known if oseltamivir affects human milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for oseltamivir phosphate and any potential adverse effects on the breastfed child from the drug or from the underlying maternal condition.
11.	Pregnancy	Use in Pregnancy	There are no adequate and well-controlled studies with oseltamivir phosphate in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Available published epidemiological data suggest that oseltamivir phosphate, taken in any trimester, is not associated with an increased risk of birth defects. However, these studies individually are limited by small sample sizes, use of different comparison groups, and some lacked information on dose, which preclude a definitive assessment of the risk
12.	Storage	What are the storage conditions?	• Store oseltamivir phosphate for oral suspension in the refrigerator for up to 17 days between 36ºF to 46ºF (2ºC to 8ºC). Do not freeze. • Store oseltamivir phosphate for oral suspension for up to 10 days at room temperature between 68°F to 77°F (20°C to 25°C). • Safely throw away any unused oseltamivir phosphate for oral suspension that is out of date or no longer needed. **Keep oseltamivir phosphate for oral suspension, and all medicines out of the reach of children**.
13.	Dispensing	How to Dispense?	As prescribed by the Physician
14.	Contraindication	What are the contraindications of (medication)?	Patients with known serious hypersensitivity to oseltamivir or any of the components of oseltamivir phosphate
Pharmaceutical Particulars			
15.	Pharmaceutical Form	How Supplied	Supplied as a white to light yellow color powder blend in a glass bottle. After constitution, the powder blend produces a white to light yellow color oral suspension. After constitution with 55 mL of water, each bottle delivers a usable volume of 60 mL of oral suspension equivalent to 360 mg oseltamivir base (6 mg/mL) (NDC 72205-060-78).

16.	Ingredients	Active and Inactive	**Active ingredient:** oseltamivir phosphate, USP **Inactive ingredients**: monosodium citrate, saccharin sodium, sodium benzoate, sorbitol, titanium dioxide, tutti-frutti flavoring, and xanthan gum.
Miscellaneous			
17.	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
18.	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
19.	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
20.	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
21.	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)