

OSELTAMIVIR PHOSPHATE FOR ORAL SUSPENSION, 6 mg per ml

S.No.	Category	Question	Answer
<b>Clinical Particulars</b>			
1.	Use/Indication	What is the product indicated for?	<p><b>Oseltamivir Phosphate</b> for Oral Suspension is an influenza neuraminidase inhibitor (NAI) indicated for:</p> <ul style="list-style-type: none"> <li>• <i>Treatment</i> 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.</li> <li>• <i>Prophylaxis</i> of influenza A and B in patients 1 year of age and older.</li> </ul> <p><b>Limitations of Use:</b></p> <ul style="list-style-type: none"> <li>• Not a substitute for annual influenza vaccination.</li> <li>• Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use.</li> <li>• Not recommended for patients with end-stage renal disease who are not undergoing dialysis.</li> </ul>
2.	Dosage	What is the recommended dosage?	<p><b>Treatment of Influenza:</b></p> <ul style="list-style-type: none"> <li>• <b>Adults and Adolescents (13 years and older):</b> 75 mg twice daily for 5 days</li> <li>• <b>Pediatric Patients (1 to 12 years of age):</b> Dosage based on weight, twice daily for 5 days</li> <li>• <b>Pediatric Patients (2 weeks to less than 1 year of age):</b> 3 mg/kg twice daily for 5 days</li> <li>• <b>Renally Impaired Adult Patients (creatinine clearance &gt;30-60 mL/min):</b> Reduce to 30 mg twice daily for 5 days</li> <li>• <b>Renally Impaired Adult Patients (creatinine clearance &gt;10-30 mL/min):</b> Reduce to 30 mg once daily for 5 days</li> <li>• <b>ESRD Patients on Hemodialysis:</b> Reduce to 30 mg immediately, then 30 mg after each hemodialysis cycle. Treatment duration should not exceed 5 days</li> <li>• <b>ESRD Patients on CAPD:</b> Reduce to a single 30 mg dose immediately</li> </ul> <p><b>Prophylaxis of Influenza:</b></p> <ul style="list-style-type: none"> <li>• <b>Adults and Adolescents (13 years and older):</b> 75 mg</li> </ul>

			<p>once daily for at least 10 days</p> <ul style="list-style-type: none"> <li>• <b>Community Outbreak:</b> 75 mg once daily for up to 6 weeks</li> <li>• <b>Pediatric Patients (1 to 12 years of age):</b> Dosage based on weight, once daily for 10 days</li> <li>• <b>Community Outbreak:</b> Dosage based on weight, once daily for up to 6 weeks</li> <li>• <b>Renally Impaired Adult Patients (creatinine clearance &gt;30-60 mL/min):</b> Reduce to 30 mg once daily</li> <li>• <b>Renally Impaired Adult Patients (creatinine clearance &gt;10-30 mL/min):</b> Reduce to 30 mg once every other day</li> <li>• <b>ESRD Patients on Hemodialysis:</b> Reduce to 30 mg immediately, then 30 mg after alternate hemodialysis cycles for the recommended duration of prophylaxis</li> <li>• <b>ESRD Patients on CAPD:</b> Reduce to 30 mg immediately, then 30 mg once weekly for the recommended duration of prophylaxis.</li> </ul>
3.	Administration	How do I take it?	<ul style="list-style-type: none"> <li>• Take oseltamivir phosphate for oral suspension exactly as your healthcare provider directs.</li> <li>• You can take oseltamivir phosphate for oral suspension with or without food. Taking it with food may reduce the chance of stomach upset.</li> <li>• If you miss a dose, take it as soon as you remember.</li> <li>• If it is less than 2 hours before your next scheduled dose, do not take the missed dose.</li> <li>• Take your next dose at the usual scheduled time.</li> <li>• Do not take two doses at the same time.</li> </ul>
4.	Administration	Use in Pediatric Population	<ul style="list-style-type: none"> <li>➤ safe and effective for the treatment of the flu in children less than 2 weeks of age.</li> <li>➤ safe and effective in the prevention of the flu in children less than 1 year of age.</li> </ul>
5.	Administration	Use in Geriatric Population	<ul style="list-style-type: none"> <li>▪ There were no overall differences in safety or effectiveness observed between older and younger subjects.</li> <li>▪ Additionally, clinical experience has not identified any significant differences in responses to the treatment between elderly individuals and younger patients.</li> </ul>
6.	Mechanism	Mechanism of Action	<p>Oseltamivir phosphate is a prodrug that is converted to its active form, oseltamivir carboxylate, through ester hydrolysis. Oseltamivir carboxylate works by inhibiting the influenza virus neuraminidase, which is essential for the release of viral particles from infected cells.</p>
7.	Warning	Warnings while using	<ul style="list-style-type: none"> <li>➤ Serious skin/hypersensitivity reactions such as Stevens-Johnson Syndrome, toxic epidermal necrolysis and erythema multiforme: Discontinue oseltamivir phosphate and initiate appropriate treatment if allergic-like reactions occur or are suspected.</li> <li>➤ Neuropsychiatric events: Patients with influenza,</li> </ul>

			including those receiving oseltamivir phosphate particularly pediatric patients, may be at an increased risk of confusion or abnormal behavior early in their illness. Monitor for signs of abnormal behavior.
8.	Lactation	Use in Lactation	There have been no reported serious adverse effects from oseltamivir exposure via breast milk. However, it is not known whether oseltamivir affects milk production.
9.	Pregnancy	Use in Pregnancy	The background risk of major birth defects and miscarriage for the indicated populations is unknown. However, all pregnancies carry a background risk of birth defects, loss, or other adverse outcomes.
10.	Precautions	Precautions while using	<ul style="list-style-type: none"> <li>❖ <b>Not recommended for people with end-stage renal disease (ESRD):</b> Oseltamivir phosphate for oral suspension is not recommended for individuals with ESRD who are not receiving dialysis.</li> <li>❖ <b>Allergic reactions:</b> Do not take oseltamivir phosphate for oral suspension if you are allergic to oseltamivir phosphate or any of the ingredients in the medication.</li> </ul>
11.	Interaction	Is there any interaction with medication?	<i>Live attenuated influenza vaccine (LAIV), intranasal:</i> Avoid administration of LAIV within 2 weeks before or 48 hours after oseltamivir phosphate use, unless medically indicated.
12.	Storage	What are the storage conditions?	<ul style="list-style-type: none"> <li>▪ Store oseltamivir phosphate for oral suspension in the refrigerator for up to 17 days between 36°F to 46°F (2°C to 8°C). Do not freeze.</li> <li>▪ 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).</li> <li>▪ Safely throw away any unused oseltamivir phosphate for oral suspension that is out of date or no longer needed.</li> </ul>
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 is it supplied?	<p><b>Oseltamivir Phosphate for Oral Suspension (Supplied as Powder):</b>          Supplied as a white to light yellow-colored powder blend in a glass bottle. After constitution, the powder blend produces a white to light yellow-colored 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)</p> <p>NDC 72205-060-78.</p>
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16.	Ingredients	Active and Inactive Ingredients	<p><b>Active:</b> Oseltamivir phosphate  <b>Inactive:</b> sorbitol, titanium dioxide, sodium benzoate, saccharin sodium, monosodium citrate, and xanthan gum.</p>
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**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; Ethanol - NMT 5000 ppm
34.	Ingredients	Does it contain dyes?	No
35.	Ingredients	Does it contain flavor?	No
36.	Ingredients	Does it contain Lactose?	No
37.	Ingredients	Does it contain Nuts?	No
38.	Ingredients	Does it contain Preservatives?	Yes; Sodium benzoate
39.	Ingredients	Does it contain Soy products?	No
40.	Ingredients	Does it contain peanut?	No
<b>Miscellaneous</b>			
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 <a href="http://NovadozPharma.com">NovadozPharma.com</a> 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 <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> .
45.	Miscellaneous	Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fill 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 <a href="http://NovadozPharma.com">NovadozPharma.com</a> ADR (authorized distributor of record) page to learn where to find our products.
46.	Miscellaneous	Manufacturer and Distributor	<p><b>Manufactured by:</b></p> <p>MSN Pharmaceuticals Inc 20 Duke Road, Piscataway-08854, NJ, USA</p>