NOVADOZ®
VALUE IN EVERY DOSE

OSELTAMIVIR PHOSPHATE CAPSULES, 30 mg, 45 mg and 75 mg

S.No.	Category	Question	Answer
		Clinical Particulars	
1	Use/Indication	What is the product indicated for?	Oseltamivir phosphate capsules 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?	See below *

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
- Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg twice daily for 5 days
- Renally 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: A single 30 mg dose should be administered 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
  In immunocompromised patients, oseltamivir phosphate capsules may be continued for up to 12 weeks
- Pediatric patients 2 weeks to less than 1 year of age: Not recommended
- 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
- Renally impaired adult patients (creatinine clearance >30-60 mL/min): Reduce to 30 mg once daily
- Renally 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

o *Not recommended for ESRD Patients not on Dialysis*

**See full prescribing information for complete details on dosing*			
3	Administration	How to administer?	• Take oseltamivir phosphate capsules exactly as your healthcare provider tells you to. • Take oseltamivir phosphate capsules with food or without food. There is less chance of stomach upset if you take oseltamivir phosphate capsules, with food. • If you cannot swallow oseltamivir phosphate capsules, your healthcare provider or pharmacist may instruct you to open oseltamivir phosphate capsules and mix the capsules contents with sweetened liquids such as chocolate syrup (regular or sugar-free), corn syrup, caramel topping, or light brown sugar (dissolved in water). **See full prescribing information for complete details on administration*
4	Administration	What if you miss a dose?	• If you miss a dose of oseltamivir phosphate capsules, 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 capsules, at your scheduled time. Do not take 2 doses at the same time.
4	Administration	Use in Pediatric Population	<u>Treatment of Influenza</u> The safety and efficacy of oseltamivir phosphate for the treatment of influenza in pediatric patients 2 weeks old to 17 years of age has been established. <u>Prophylaxis of Influenza</u> The safety and efficacy of oseltamivir phosphate for the prophylaxis of influenza in pediatric patients 1 year to 17 years old has been established. The safety and efficacy of oseltamivir phosphate for prophylaxis of influenza have not been established for pediatric patients less than 1 year of age. **For more information, please refer to full prescribing information*
5	Administration	Use in Geriatric Population	<u>Treatment of Influenza</u> There are no overall differences in safety or effectiveness was observed between elderly patients and younger patients who are treated with oseltamivir phosphate. Other reported clinical experience has not identified differences in responses between the elderly and younger subjects. <u>Prophylaxis of Influenza</u> There are no overall differences in safety or effectiveness were observed between elderly patients and younger patients who are treated with oseltamivir phosphate. Other reported

			clinical experience has not identified differences in responses between the elderly and younger subjects. **For more information, please refer to full prescribing information*
6	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.
7	Warning	Warnings and Precautions	• 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. • 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 their illness. Monitor for signs of abnormal behaviour. • Risk of Bacterial Infections: There is no evidence for efficacy of oseltamivir phosphate in any illness caused by pathogens other than influenza viruses. Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. Oseltamivir phosphate has not been shown to prevent such complications. Prescribers should be alert to the potential for secondary bacterial infections and treat them as appropriate. • Fructose Intolerance in Patients with Hereditary Fructose Intolerance: Fructose can be harmful to patients with hereditary fructose intolerance. In patients with hereditary fructose intolerance receiving above the daily maximum limit of sorbitol, may cause dyspepsia and diarrhea.
8	Lactation	Use in Lactation	Before you take oseltamivir phosphate capsules, tell your healthcare provider if you are breastfeeding or plan to breastfeed. Oseltamivir phosphate can pass into breast milk in small amounts. **For more information, please refer to full prescribing information*
9	Pregnancy	Use in Pregnancy	Before you take oseltamivir phosphate capsules, tell your healthcare provider if you are pregnant or plan to become pregnant. Available information indicates that oseltamivir phosphate

			capsules does not increase the risk of birth defects. **For more information, please refer to full prescribing information*
10	Storage	What are the storage conditions?	Store the capsules at 25ºC (77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF).
11	Contraindication	What are the contraindications of (medication)?	Oseltamivir phosphate is contraindicated in patients with known serious hypersensitivity to oseltamivir or any component of the product. Severe allergic reactions have included anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme. **For more information, please refer to full prescribing information*
12	Drug Interactions	Any Drug Interactions?	Live attenuated influenza vaccine (LAIV), intranasal: Avoid administration of LAIV within 2 weeks before or 48 hours after oseltamivir phosphate use, unless medically indicated. No dose adjustments are needed for either oseltamivir or the concomitant drug when coadministering oseltamivir with amoxicillin, acetaminophen, aspirin, cimetidine, antacids (magnesium and aluminum hydroxides and calcium carbonates), rimantadine, amantadine, or warfarin. **For more information, please refer to full prescribing information*
Pharmaceutical Particulars			
13	Pharmaceutical Form	How is it supplied?	**30-mg capsules** (30 mg free base equivalent of the phosphate salt): Size "4" hard gelatin capsules with light yellow opaque colour body with black colour band, imprinted with "M" and light yellow opaque colour cap imprinted with "30 mg". Available in blister packages of 10 (NDC-72205-042-11) **45-mg capsules** (45 mg free base equivalent of the phosphate salt): Size "4" hard gelatin capsules with grey opaque colour body with black colour band, imprinted with " M " and grey opaque colour cap imprinted with "45mg". Available in blister packages of 10 (NDC-72205-043-11) **75-mg capsules** (75 mg free base equivalent of the phosphate salt): Size "2" hard gelatin capsules with grey opaque colour body with black colour band, imprinted with "M" and light yellow opaque colour cap imprinted with "75 mg. Available in blister packages of 10 (NDC-72205-044-11).

14	Ingredients	Active and Inactive	Active ingredient: Oseltamivir phosphate Inactive ingredients: In addition to the active ingredient, each capsule contains croscarmellose sodium, povidone K30, pregelatinized starch, sodium stearyl fumarate and talc. • The 30 mg capsule shell contains gelatin, iron oxide red, iron oxide yellow, and titanium dioxide. • The 45 mg capsule shell contains gelatin, iron oxide black, and titanium dioxide. • The 75 mg capsule shell contains gelatin, iron oxide black, iron oxide red, iron oxide yellow, and titanium dioxide, each capsule is printed with black ink, which includes shellac, iron oxide black, propylene glycol and potassium hydroxide.
Allergens			
15	Ingredients	Does it contain Gluten?	No
16	Ingredients	Does it contain alcohol?	Oseltamivir Phosphate API contains Methonal NMT 3000 PPM
17	Ingredients	Does it contain Starch?	Starch used in this product derived from maize starch/corn starch
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	Are all excipients are free from human or animal origin?	No. Gelatin used in capsules is derived from healthy bovines
24	Ingredients	Other Substances	Oseltamivir Phosphate Capsules 30 mg, 45 mg and 75 mg does not contain Dairy, Latex, Casein, Whey, Rye, Sugar, Oats, Wheat, Spelt, Barley and Rennet.
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	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.

29	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
30	Miscellaneous	May I know where is this product manufactured?	**Manufactured by:** MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by:** Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714