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**INDICATIONS AND USAGE**

1.1 Treatment of Influenza
Oseltamivir Phosphate Capsules, USP are indicated for the treatment of acute, uncomplicated illness due to influenza A and B infection in patients 2 weeks of age and older who have been symptomatic for no more than 48 hours.

1.2 Prophylaxis of Influenza
Oseltamivir Phosphate Capsules, USP are indicated for the prophylaxis of influenza A and B infection in patients 2 weeks of age and older who have been symptomatic.

**Limitations of Use**

- Oseltamivir Phosphate Capsules, USP are not a substitute for annual influenza vaccination or other preventive measures such as good hand hygiene and staying away from persons with acute respiratory illness.
- Oseltamivir Phosphate Capsules, USP are not a substitute for annual influenza vaccination or other preventive measures such as good hand hygiene and staying away from persons with acute respiratory illness.

**How Supplied/Storage and Handling**

- Oseltamivir Phosphate Capsules, USP are supplied in bottles of 30, 45, 75, and 150 capsules.
- Store at controlled room temperature 15°C to 30°C (59°F to 86°F).
- Keep out of reach of children.

**PATIENT COUNSELING INFORMATION**

- Oseltamivir Phosphate Capsules, USP should be taken orally with or without food.
- Oseltamivir Phosphate Capsules, USP should be taken as soon as possible after the onset of illness.
- Oseltamivir Phosphate Capsules, USP should be taken for no more than 48 hours.
- Oseltamivir Phosphate Capsules, USP should be taken for a full course of treatment, usually for 5 days.

**ADVERSE REACTIONS**

- The most common adverse reactions (>1% and more common than with placebo) are nausea, vomiting, headache, and pain.
- Patients with known serious hypersensitivity to oseltamivir or any of the components of oseltamivir phosphate capsules (oral suspension) should not use oseltamivir phosphate capsules.
- Serious skin/hypersensitivity reactions such as Stevens-Johnson Syndrome, toxic epidermal necrolysis, and erythema multiforme have been reported in patients receiving oseltamivir phosphate capsules.

**CONTRAINDICATIONS**

- Oseltamivir Phosphate Capsules, USP are contraindicated in patients with known serious hypersensitivity to oseltamivir or any of the components of oseltamivir phosphate capsules (oral suspension).
- Oseltamivir Phosphate Capsules, USP are not a substitute for annual influenza vaccination or other preventive measures such as good hand hygiene and staying away from persons with acute respiratory illness.

**WARNINGS AND PRECAUTIONS**

- Oseltamivir Phosphate Capsules, USP should be used with caution in patients with serious underlying medical conditions or in any patient whose underlying medical condition may increase the risk of influenza complications.
- Oseltamivir Phosphate Capsules, USP should be used with caution in pregnant women and in breastfeeding women.
- Oseltamivir Phosphate Capsules, USP should be used with caution in patients with renal or hepatic impairment.

**DRUG INTERACTIONS**

- Oseltamivir Phosphate Capsules, USP may interact with other drugs, particularly those that might impair the renal or hepatic metabolism.
- Oseltamivir Phosphate Capsules, USP should not be used with other antiviral agents.

**OVERDOSAGE**

- Oseltamivir Phosphate Capsules, USP overdosage may result in nausea, vomiting, headache, and pain.
- Oseltamivir Phosphate Capsules, USP overdosage may result in nausea, vomiting, headache, and pain.

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**FULL PRESCRIBING INFORMATION: CONTENTS**

1. INDICATIONS AND USAGE
2. DOSAGE AND ADMINISTRATION
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**REFERENCES:**

- The full prescribing information for Oseltamivir Phosphate Capsules, USP is available on the Zydus Pharmaceuticals (USA) Inc. website.
- Updated on [Date].

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**REVISED:** [Date]
2.2Dosage and Administration Overview

Advisory information on oseltamivir phosphate for the treatment of influenza in patients 1 year of age or older [see Dosage and Administration (2.2)] or for prophylaxis of influenza in patients 1 year of age or older [see Dosage and Administration (2.3)].

The capsules may be taken with or without food; however, tolerability may be enhanced if oseltamivir phosphate capsules are taken with food. Adjust the oseltamivir phosphate capsules dosage in patients with moderate or severe renal impairment [see Dosage and Administration (2.4)].

For patients who cannot swallow capsules, oseltamivir phosphate for oral suspension is the preferred formulation. When oseltamivir phosphate for oral suspension is not available from wholesaler or the manufacturer, oseltamivir phosphate capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup, corn syrup, caramel topping, or light brown sugar (dissolved in water). During emergency situations and when neither the oral suspension nor the appropriate capsules are available, the pharmacist may prepare an emergency supply of oral suspension from oseltamivir phosphate 75 mg capsules [see Dosage and Administration (2.4)].

2.3Recommended Dosage for Treatment of Influenza

Initiate treatment with oseltamivir phosphate capsules within 48 hours of influenza symptom onset.

Adults and Adolescents (13 years of age and older)

The recommended oral dosage of oseltamivir phosphate for treatment of influenza in adults and adolescents 13 years and older is 75 mg twice daily (one 75 mg capsule twice daily) for 5 days.

Pediatric Patients (2 weeks of age through 12 years of age)

Table 1 displays the recommended oral dosage of oseltamivir phosphate for treatment of influenza in pediatric patients 2 weeks of age through 12 years of age and provides information about prescribing the capsule or the formulation for oral suspension.

2.4Dosage for Prophylaxis of Influenza

Initiate post-exposure prophylaxis with oseltamivir phosphate capsules within 48 hours following close contact with an infected individual. Initiate seasonal prophylaxis with oseltamivir phosphate capsules during a community outbreak.

Adults and Adolescents (13 years of age and older)

The recommended oral dosage of oseltamivir phosphate capsules for prophylaxis of influenza in adults and adolescents 13 years and older is 75 mg once daily (one 75 mg capsule once daily) for at least 10 days following close contact with an infected individual and up to 8 weeks during a community outbreak. In immunocompromised patients, oseltamivir phosphate capsules may be continued for up to 2 weeks (not use in Specific Populations (8.9)). The duration of post-exposure prophylaxis for up to 10 days following close contact with an infected individual and up to 8 weeks during a community outbreak [see Use in Specific Populations (8.6) and Clinical Studies (14.2)].

Table 1Oseltamivir Phosphate Dosage Recommendations in Pediatric Patients for Treatment and Prophylaxis of Influenza

Pediatric Patients (1 year to 12 years of age)

The following directions are provided for use only during emergency situations and when neither the oral suspension nor the appropriate capsules are available. The pharmacist may prepare an emergency supply of oral suspension from oseltamivir phosphate 75 mg capsules [see Dosage and Administration (2.4)].

Table 2 Recommended Dosage Modifications for Treatment

Table 3Emergency Preparation: Volume of Prepared Oral Suspension (6 mg per mL) Based on Oral

2.5Dosage in Pediatric Patients

Patients from 2 Weeks to less than 1 Year of Age

Table 1 displays the recommended oral dosage of oseltamivir phosphate capsules for prophylaxis of influenza in pediatric patients 1 year to 12 years of age based on weight and provides information about prescribing the capsule or the formulation for oral suspension.

Pediatric Patients (1 year to 12 years of age)

2.6Dosage in Patients with Renal Impairment

Table 2 displays the dosage recommendations for the treatment and prophylaxis of influenza in adults with various stages of renal impairment [see Use in Specific Populations (8.2)] and describes the dosage adjustment for multiple dosing in ESRD patients.

Table 2 Recommended Dosage Modifications for Treatment and Prophylaxis of Influenza in Adults with Renal Impairment or End Stage Renal Disease (ESRD) on Dialysis

Table 3Emergency Preparation: Volume of Prepared Oral Suspension (6 mg per mL) Based on Oral

2.7Dosage in Peritoneal Dialysis Patients

Table 2 displays the dosing recommendations for the treatment and prophylaxis of influenza in patients 1 year of age through 11 years of age, based on weight and provides information about prescribing the capsule or the formulation for oral suspension.

Pediatric Patients from 2 Weeks to less than 1 Year of Age

2.8Dosage in Patients on Chronic Ambulatory Peritoneal Dialysis

Table 2 displays the dosing recommendations for the treatment and prophylaxis of influenza in patients 1 year of age through 11 years of age, based on weight and provides information about prescribing the capsule or the formulation for oral suspension.

Pediatric Patients from 2 Weeks to less than 1 Year of Age

2.9Dosage in Continuous Ambulatory Peritoneal Dialysis Patients

Table 2 displays the dosing recommendations for the treatment and prophylaxis of influenza in patients 1 year of age through 11 years of age, based on weight and provides information about prescribing the capsule or the formulation for oral suspension.

Pediatric Patients from 2 Weeks to less than 1 Year of Age
Step 2: Preparation or treatment with one of the following vehicles (other vehicles have not been studied). Cherry Syrup (Humco®), One Swallow SF (Paddock Laboratories), or simple syrup. Determine the number of capsules and the amount of water and vehicle needed to prepare the total volume (see Table 4) of prepared oral suspensions (5 mg per mL) for a complete treatment or prophylaxis course (see Table 4).

Table 4 Emergency Preparation: Number of Oseltamivir Phosphate 75 mg Capsules and Amount of Water and Vehicle Needed to Prepare the Total Volume of a Prepared Oral Suspension (5 mg per mL)

<table>
<thead>
<tr>
<th>Total Volume of Prepared Oral Suspension</th>
<th>Number of Oseltamivir Phosphate 75 mg Capsules (Total Strength)*</th>
<th>Volume of Cherry Syrup (Humco®) OR One Swallow SF (Paddock Laboratories) OR simple syrup</th>
<th>Amount of Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.5 mL</td>
<td>1 (125 mg)</td>
<td>2.5 mL</td>
<td>35 mL</td>
</tr>
<tr>
<td>75 mL</td>
<td>2 (250 mg)</td>
<td>5 mL</td>
<td>70 mL</td>
</tr>
<tr>
<td>100 mL</td>
<td>3 (375 mg)</td>
<td>7.5 mL</td>
<td>95 mL</td>
</tr>
<tr>
<td>125 mL</td>
<td>4 (500 mg)</td>
<td>10 mL</td>
<td>110 mL</td>
</tr>
<tr>
<td>150 mL</td>
<td>5 (625 mg)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Includes enough to ensure all doses can be delivered.

Step 3: Follow the instructions below for preparing the 75 mg oseltamivir phosphate capsules to produce the oral suspension (5 mg per mL).

1. Place the specified amount of water into a polyethylene terephthalate (PET) or glass bottle (see Table 4). Combustion in other bottle types is not recommended because there is no stability data with other bottle types.
2. Carefully separate the capsule body and cap and pour the contents of the required number of oseltamivir phosphate 75 mg capsules into the PET or glass bottle.
3. Gently swirl the suspension to ensure adequate wetting of the oseltamivir phosphate powder for at least 2 minutes.
4. Slowly add the specified amount of vehicle to the bottle.
5. Close the bottle using a child-resistant cap and shake well for 30 seconds to completely dissolve the active drug and to ensure homogeneous distribution of the dissolved drug in the resulting suspension. The active drug, oseltamivir phosphate, readily dissolves in the specified vehicles. The suspension is caused by inert ingredients of oseltamivir phosphate capsules which are insoluble in these vehicles.
6. Put an auxiliary label on the bottle indicating “Shake Well Before Use.”
7. Insert the parent or caregiver into any unusual suspensions remaining in the bottle following preparation or any unusual suspensions remaining in the bottle following administration or any other required information to be in compliance with all State and Federal Pharmacy Regulations. Place an appropriate expiration date on the label according to conditions below.
8. Include the recommended dosage or the pharmacy label as per 7 tables 1 and 2 on Dosage and Administration (2.2, 2.3, and 2.4).
9. Store the prepared oral suspension in glass or PET bottles either:
   - In refrigerator (2°C to 8°C [36°F to 46°F]) Stable for 5 weeks when stored in refrigerator.
   - At room temperature (25°C [77°F]) Stable for 5 days when stored at room temperature.

OSOLETAMIVIR PHOSPHATE CAPSULES

3 DOSAGE FORMS AND STRENGTHS

Oseltamivir Phosphate Capsules: 30 mg capsules (10 mg free base equivalent of the phosphate salt) White Opague/White Opague Capsule, imprinted with black ink “N” on the body and black ink “1000” on the cap.
45 mg capsules (45 mg free base equivalent of the phosphate salt) Light Grey Opague/Light Blue Opague Capsule, imprinted with black ink “N” on the body and black ink “0005” on the cap.
75 mg capsules (75 mg free base equivalent of the phosphate salt) White Opague/Light Grey Opague Capsule, imprinted with black ink “N” on the body and black ink “1010” on the cap.

4 CONTRAINDICATIONS

Oseltamivir phosphate capsules are 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 [see Warnings and Precautions (5.2)].

5 WARNINGS AND PRECAUTIONS

5.1 Serious Skinf/Hypersensitivity Reactions

Cases of anaphylaxis and skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme have been reported in postmarketing experience with oseltamivir phosphate capsules. See Warnings and Precautions (5.1).

5.2 Neuropsychiatric Events

There have been postmarketing reports of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving oseltamivir phosphate capsules [see Adverse Reactions (6.2)]. Because these events were reported voluntarily during clinical trials, estimates of frequency cannot be made but they appear to be uncommon based on oseltamivir phosphate capsules usage data. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of oseltamivir phosphate capsules to these events has not been established. Delirium can be associated with a variety of neuropsychiatric events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. Delirium may occur in the setting of encephalitis or encephalopathy but has not been directly associated with oseltamivir phosphate capsules in these patients. Delirium may be associated with a variety of neuropsychiatric events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. Delirium may occur in the setting of encephalitis or encephalopathy but has not been directly associated with oseltamivir phosphate capsules in these patients. Delirium may be associated with a variety of neuropsychiatric events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. Delirium may occur in the setting of encephalitis or encephalopathy but has not been directly associated with oseltamivir phosphate capsules in these patients. Delirium may be associated with a variety of neuropsychiatric events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes.

5.3 Risk of Bacterial Infections

There is no evidence for efficacy of oseltamivir phosphate capsules in any illness caused by pathogens other than influenza viruses. Seasonal bacterial infections may begin with influenza-like symptoms or may occur with or occur as complications during the course of influenza. Oseltamivir phosphate capsules have not been shown to prevent such complications. Prescribers should be alert to the potential for secondary bacterial infections and treat them as appropriate.

ADVERSE REACTIONS

The following serious adverse reactions are discussed below and elsewhere (side labeling):

- Serious skin/hypersensitivity reactions [see Warnings and Precautions (5.2)]
- Neuropsychiatric events [see Warnings and Precautions (5.2)]

4.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reactions observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse Reactions from Treatment and Prophylaxis Trials in Adults and Adolescent Subjects (13 years of age and older)

The overall safety profile of oseltamivir phosphate is based on data from 2,646 adults and adolescent subjects that received the recommended dosage of 75 mg orally twice daily for 5 days for treatment of influenza and 1,565 adults and adolescent subjects that received the recommended dosage of 75 mg orally once daily for 5 weeks for prophylaxis of influenza in clinical trials.

The most common adverse reactions in the postmarketing and published prophylaxis trials in adults and adolescents are displayed in Table 5. The majority of adverse reactions were reported on single occasions, occurred on either the first or second treatment day and resolved spontaneously within 1-2 days. This summary includes only adverse reactions that occurred at a rate at least twice that of placebo.

Table 5 Adverse Reactions Occurring in ≥1% of Adults and Adolescents (13 years of age and older) in Treatment and Prophylaxis Trials

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo</th>
<th>Oseltamivir Phosphate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile illness</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Infected respiratory illness</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Headache</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Asthenia</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Rash</td>
<td>0%</td>
<td>1%</td>
</tr>
</tbody>
</table>

*Any reaction not listed here occurs at a frequency of ≤1% of the placebo group.
Based on limited published data, oseltamivir and oseltamivir carboxylate have been shown to be present in breast milk. Oseltamivir carboxylate was observed at doses ≤500 mg/kg/day, resulting in systemic drug exposures (based on AUC for oseltamivir carboxylate) 190 times human exposures at the maximum recommended human dose (MRHD) of oseltamivir phosphate.

Among the 180 pediatric subjects aged 1 year to 12 years who received oseltamivir phosphate at doses of 30 to 60 mg once daily for 10 days (age post-exposure influenza prophylaxis study; median age 6 years [n = 40]), vomiting was the most frequent adverse reaction (7% on oseltamivir phosphate versus 2% in the placebo group).

Adverse reactions to Treatment (Table 1) in Pediatric Subjects 1 to 12 years of age

A total of 1,481 pediatric subjects (including otherwise healthy pediatric subjects aged 1 year to 12 years and asthmatic pediatric subjects aged 6 to 12 years) participated in clinical trials of oseltamivir phosphate for the treatment of influenza. A total of 259 pediatric subjects received treatment with oseltamivir phosphate for oral suspension either at a 2 mg/kg twice daily for 5 days or weight-based dosing. Vomiting was the only adverse reaction reported at a frequency of ≥1% in subjects receiving oseltamivir phosphate (16%) compared to placebo (5%).

The following adverse reactions have been identified during post-approval use of oseltamivir phosphate capsules.

The concurrent use of oseltamivir phosphate capsules with live attenuated influenza vaccine (LAIV) immunization has not been evaluated. However, because of the potential for oseltamivir phosphate capsules to inhibit replication of live virus vaccine and possibly reduce the efficacy of LAIV, avoid administration of LAIV within 2 weeks before or 48 hours after oseltamivir phosphate capsules administration, unless medically indicated.

**Influenza Vaccine**

Vaccine-induced influenza vaccine can be administered at any time relative to use of oseltamivir phosphate capsules.

**7. Drug Interactions**

**7.1 Influenza Vaccines**

The concurrent use of oseltamivir phosphate capsules with live attenuated influenza vaccine (LAIV) immunization has not been evaluated. However, because of the potential for oseltamivir phosphate capsules to inhibit replication of live virus vaccine and possibly reduce the efficacy of LAIV, avoid administration of LAIV within 2 weeks before or 48 hours after oseltamivir phosphate capsules administration, unless medically indicated.

**Vaccine Related Influenza Virus**

Influenza vaccine administration time relative to use of oseltamivir phosphate capsules.

**7.2 Drugs Without Clinically Significant Drug Interactions with Oseltamivir Phosphate Capsules**

No dose adjustments are needed for either oseltamivir or the concomitant drug when coadministering oseltamivir phosphate capsules.

**8 USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Risk Summary**

There are no adequate and well-controlled studies with oseltamivir phosphate capsules in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Available published epidemiological data suggest that oseltamivir phosphate capsules, taken by 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 to pregnant women.

**Clinical Considerations**

**Disease-Associated Maternal and/or Embryo/Fetal Risk**

Pregnant women are at higher risk of severe complications from influenza, which may lead to adverse pregnancy and/or fetal outcomes including maternal death, still births, birth defects, preterm delivery, low birth weight, and small for gestational age.

**Data**

Published prospective and retrospective observational studies of more than 5,000 women exposed to oseltamivir during pregnancy, including more than 1,000 women exposed in the first trimester suggest that the observed rate of congenital malformations was not increased above the rate in the general comparison population, regardless of when therapy was administered during the gestational period. However, individual, none of these studies had adequate sample sizes and some lacked information on dose, which preclude a definitive assessment of the risk.

**Animal Data**

Oseltamivir was administered orally during organogenesis to pregnant rats (at 50, 250, or 1,500 mg/kg/day) and rabbits (at 50, 150, or 500 mg/kg/day) from gestation days 6 to 17. A total of 259 pediatric subjects received treatment with oseltamivir phosphate for oral suspension either at a 2 mg/kg twice daily for 5 days or weight-based dosing. Vomiting was the only adverse reaction reported at a frequency of ≥1% in subjects receiving oseltamivir phosphate (16%) compared to placebo (5%).

Oseltamivir was administered orally during organogenesis to pregnant rats (at 50, 250, or 1,500 mg/kg/day) and rabbits (at 50, 150, or 500 mg/kg/day) from gestation days 6 to 17. The observed adverse reactions were observed at doses of 1500 mg/kg/day. No adverse maternal or offspring effects were observed at doses of 500 mg/kg/day, resulting in systemic drug exposures (based on AUC for oseltamivir carboxylate) 44 times human exposures at the MRHD of oseltamivir phosphate.

**8.2 Lactation**

**Risk Summary**

Based on limited published data, oseltamivir and oseltamivir carboxylate have been shown to be present in breast milk. Oseltamivir carboxylate was observed at doses ≤500 mg/kg/day, resulting in systemic drug exposures (based on AUC for oseltamivir carboxylate) 190 times human exposures at the MRHD of oseltamivir phosphate.
Oseltamivir is an antiviral drug with activity against influenza virus. The molecular weight is 312.4 for oseltamivir free base and 624.8 for oseltamivir phosphate.

The safety and efficacy of oseltamivir phosphate for the treatment of influenza in pediatric patients less than 2 weeks of age have not been established.

The safety and efficacy of oseltamivir phosphate for prophylaxis of influenza in pediatric patients less than 2 weeks of age have not been established.

The safety and efficacy of oseltamivir phosphate capsules for the treatment of influenza in pediatric patients less than 2 years of age is supported by one randomized, open-label, post-exposure household prophylaxis trial including pediatric patients 6 to 12 years of age who received 75 mg of oseltamivir phosphate for (oral suspension) on powders or crushed once daily for 10 days [see Clinical Studies (14.2,3)]. Additional safety information was provided in a 4-week seasonal prophylaxis (community outbreaks) safety study in 49 patients 1 to 12 years of age. The safety and efficacy of oseltamivir phosphate for prophylaxis of influenza have not been established for pediatric patients less than 1 year of age.

Oseltamivir phosphate capsules are not recommended for patients with ESRD not undergoing dialysis or with end-stage renal disease (ESRD) undergoing routine hemodialysis or continuous peritoneal dialysis treatment [see Dosage and Administration (2.2)].

In pediatric patients 1 year to 12 years of age, the oseltamivir plasma concentrations in these subjects were similar to or higher than the oseltamivir plasma concentrations observed in older pediatric subjects and adults [see Clinical Pharmacology (12.3) and Clinical Studies (14.3,4)].

Additional safety information was provided in a 4-week seasonal prophylaxis (community outbreaks) safety study in 49 patients 1 to 12 years of age.
Oseltamivir is absorbed from the gastrointestinal tract after oral administration of oseltamivir phosphate and is extensively converted pre-systemically by esterases to oseltamivir carboxylate. At least 75% of an oral dose reaches the systemic circulation as oseltamivir and less than 5% of the oral dose reaches the systemic circulation as oseltamivir (see Table 5).

Table 6 Mean (% CV) Pharmacokinetic Parameters of Oseltamivir and Oseltamivir Carboxylate Following Multiple Dosing of 75 mg Capsules Twice Daily (n=20)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Oseltamivir</th>
<th>Oseltamivir Carboxylate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tmax (h)</td>
<td>0.50 (0.50)</td>
<td>0.50 (0.50)</td>
</tr>
<tr>
<td>Cmax (ng/mL)</td>
<td>184 (184)</td>
<td>184 (184)</td>
</tr>
<tr>
<td>AUC0-24h (ng·h/mL)</td>
<td>184 (184)</td>
<td>184 (184)</td>
</tr>
</tbody>
</table>

Plasma concentrations of oseltamivir carboxylate are proportional to doses up to 500 mg oseltamivir daily (approximately 6.7 times the maximum recommended oseltamivir phosphate capsule dosage) (see Dosage and Administration (2)). Co-administration with food had no significant effect on the peak plasma concentration (55 ng/mL under fasted condition and 64 ng/mL under fed condition) and the area under the plasma concentration curve (AUC) was similar under fasted and fed conditions, but higher in subjects under fed conditions of oseltamivir carboxylate.

Elimination

Oseltamivir is primarily (90%) eliminated by the active metabolite, oseltamivir carboxylate. Plasma concentrations of oseltamivir declined with a half-life of 1 to 3 hours in subjects after oral administration. Oseltamivir carboxylate is not further metabolized and is eliminated unchanged in the urine. Plasma concentrations of oseltamivir carboxylate declined with a half-life of 6 to 10 hours in former subjects after oral administration.

Metabolism

Oseltamivir is extensively converted to the active metabolite, oseltamivir carboxylate, by esterases located predominantly in the liver. Oseltamivir carboxylate is not further metabolized. Neither oseltamivir nor oseltamivir carboxylate is a substrate for, or inhibitor of, cytochrome P450 isoenzymes.

Excretion

Oseltamivir carboxylate is eliminated entirely (95%) by renal excretion. Renal clearance (18.8 L/h) exceeded glomerular filtration rate (12.5 L/h), indicating that secretion (via organic anion transporters) occurs in addition to glomerular filtration. Less than 20% of an oral radiolabeled dose eliminated in feces.

Specific Populations

Pregnant Women

Administration of 100 mg of oseltamivir phosphate twice daily (approximately 1.3 times the maximum recommended dosage) for 5 days to subjects with various degrees of renal impairment showed that exposure to oseltamivir carboxylate is inversely proportional to the renal function.

Regimens or dosing pharmacokinetic parameters were described for patients with varying degrees of renal function including ESRD patients on hemodialysis. Median simulated exposures of oseltamivir carboxylate for recommended treatment and prophylaxis regimens are provided in Table 7. The pharmacokinetics of oseltamivir have not been studied in ESRD patients not undergoing dialysis (see Indications and Usage (1.4) and Use in Specific Populations (8.4)).

Pediatric Subjects (1 year to 12 years of age)

The pharmacokinetics of oseltamivir and oseltamivir carboxylate have been evaluated in two open-label studies of pediatric subjects less than one year of age (n=122) infected with influenza. Apparent clearance of the active metabolite decreases linearly with increasing age.
The antiviral activity of oseltamivir carboxylate against laboratory strains and clinical isolates of influenza virus was determined in cell culture. The concentrations of oseltamivir carboxylate required for inhibition of influenza virus replication in cell culture were highly variable depending on virus assayed and the virus involved. The 50% effective concentration (EC50) and EC90 were in the range of 0.008 micromolar to greater than 25 micromolar and 0.014 micromolar to greater than 100 micromolar, respectively. The relationship between the antiviral activity in cell culture, inhibitory activity in the mouse model, and the inhibition of influenza virus replication in humans has not been established.


table

| Neuraminidase Amino Acid Substitutions Associated with Reduced Susceptibility to Oseltamivir |
|-----------------------------------|----------------------------------|----------------------------------|

All numbering is N2, except where indicated.

Cross-resistance

Cross-resistance between oseltamivir and amantadine has been observed in influenza virus isolates from clinical studies of oseltamivir carboxylate and amantadine. However, the clinical relevance of phenotypic cross-resistance between oseltamivir phosphate capsules and amantadine has not been established.

Immunogenicity

No influenza virus/neosubunit interaction study has been conducted. Studies of naturally acquired and experimental influenza, treatment with oseltamivir phosphate capsules did not impair normal humoral antibody response to infection.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No single amino acid substitution has been identified that could confer cross-resistance between the neuraminidase (N1 numbering) or the NA (N2 numbering) resistance-associated substitutions observed in influenza A viruses resistant to both oseltamivir and amantadine. However, a virus may carry one neosubunit inhibitor-associated substitution in neuraminidase and an NA (or NA inhibitor-associated substitution in NA and may therefore be resistant to both classes of inhibitors. The clinical relevance of phenotypic cross-resistance evaluation has not been established.

Immunogenicity

No influenza virus/neosubunit interaction study has been conducted. Studies of naturally acquired and experimental influenza, treatment with oseltamivir phosphate capsules did not impair normal humoral antibody response to infection.

13.2 Treatment of Influenza

Adolescents and Adults with Chronic Respiratory Disease

A double-blind, placebo-controlled, multicenter trial was unable to demonstrate efficacy of oseltamivir phosphate capsules (75 mg twice a day for 5 days) in the treatment of influenza in adult and adolescent subjects (13 years or older) with chronic cardiac (excluding chronic idiopathic hypertension) or respiratory disease, as measured by time to alleviation of all symptoms. However, in patients treated with oseltamivir phosphate capsules there was a more rapid resolution of fever and headache. No differences in the incidence of influenza complications were observed between the treatment and placebo groups in this population.
![Image of a document page](image-url)

**Important Dosing Information**

**Precautions (5.2)**

Advise patients and/or caregivers of the risk of neuropsychiatric events in oseltamivir phosphate capsules.

**Neuropsychiatric Events**

Immediate medical attention if an allergic-like reaction occurs or is suspected. Instruct patients and/or caregiver to stop oseltamivir phosphate capsules and seek medical advice. Separate analysis by gender showed no differences in the clinical efficacy of oseltamivir phosphate capsules and female pediatric patients.

**Pediatric Subjects (1 year to 12 years of age)**

Two open-label trials evaluated the safety and pharmacokinetics of oseltamivir and oseltamivir carboxylate in influenza-infected pediatric subjects 2 weeks to less than 1 year of age (including premature infants at least 30 weeks post conceptional age). Subjects received oseltamivir phosphate at doses ranging from 3 to 3.5 mg per kg body weight daily for 5 days on consecutive days. These clinical trials were not designed to evaluate clinical efficacy or statistical relevance.

Of the 136 subjects under the age of 1 year enrolled and dosed in the trials, the majority of the subjects were male (58%), white (79%), non-Hispanic (74%), full term (75%) and infected with influenza A (89%). Pharmacokinetic data indicated that a dose of 3 mg per kg body weight daily led to plasma concentrations in children that were observed in older pediatric subjects and adults receiving the approved dose and provided the basis for approval for use in specific populations (8.4) and use in specific populations (8.6).

**14.2 Prophylaxis of Influenza**

**Adults and Adoelre Subjects (13 years of age and older)**

The efficacy of oseltamivir phosphate in preventing naturally occurring influenza illness has been demonstrated in three seasonal prophylaxis (community outbreak) clinical trials and one post-exposure prophylaxis trial in household contacts. The efficacy endpoint for all of these trials was the incidence of laboratory-confirmed influenza defined as meeting all the following criteria (all signs and symptoms must have had to be present within 24 hours):

- acute temperature greater than or equal to 99.0°F (37.2°C).
- at least one respiratory symptom (cough, nasal secretion, and/or sore throat).
- at least one gastrointestinal symptom (nausea and/or vomiting and/or diarrhea).
- either positive virus isolation or a four-fold increase in virus antibody titers from baseline.

In a pooled analysis of two seasonal prophylaxis trials in healthy unvaccinated adults (aged 18 to 65 years), oseltamivir phosphate 75 mg once daily or placebo taken orally for 42 days during a community outbreak reduced the incidence of laboratory-confirmed influenza by 30% (27/95) compared to the placebo group (3%). A secondary analysis was performed using the same clinical symptoms and RT-PCR for influenza virus and showed a 1-day reduction in the median time to improvement in influenza illness (p=0.05).

The efficacy of oseltamivir phosphate in preventing naturally occurring influenza illness was demonstrated in a randomized, placebo-controlled post-exposure prophylaxis trial in household contacts that included pediatric subjects aged 13 years or younger, 15% of whom were aged 1 year or younger. All subjects were vaccinated, had had one or more upper respiratory tract infections in the 6 months prior to randomization, and had chronic obstructive pulmonary disease, respectively. In the oseltamivir phosphate group, subjects were randomized to oseltamivir phosphate capsules 75 mg once daily or placebo taken orally for 42 days. The incidence of laboratory-confirmed influenza was 4% (12/272) in the placebo-treated subjects compared to less than 1% (0.7%) in the oseltamivir phosphate-treated subjects.

In the post-exposure prophylaxis trial in household contacts aged 13 years or older of an index influenza case, oseltamivir phosphate 75 mg once daily or placebo was administered within 48 hours of onset of symptoms in the index case and continued for 7 days. Index cases did not receive oseltamivir phosphate capsules treatment. The incidence of laboratory-confirmed influenza was 12% (24/205) in the placebo-treated subjects compared to 2% (2/105) in the oseltamivir phosphate-treated subjects.

**Pediatric Subjects (1 year to 12 years of age)**

The efficacy of oseltamivir phosphate in preventing naturally occurring influenza illness was demonstrated in a randomized, placebo-controlled pediatric prophylaxis trial. Subjects received oseltamivir phosphate for oral suspension 30 to 60 mg taken orally once daily for 10 days. The efficacy parameter was the incidence of laboratory-confirmed influenza defined as meeting all the following criteria (all signs and symptoms must have been present within 24 hours):

- acute temperature greater than or equal to 99.0°F (37.2°C).
- at least one respiratory symptom (cough, nasal secretion, and/or sore throat).
- at least one gastrointestinal symptom (nausea and/or vomiting and/or diarrhea).
- either positive virus isolation or a four-fold increase in virus antibody titers from baseline.

In the post-exposure prophylaxis trial in household contacts of an index influenza case, oseltamivir phosphate capsules 75 mg once daily or placebo taken orally for 42 days. The incidence of laboratory-confirmed influenza was 4% (12/272) in the placebo-treated subjects compared to less than 1% (0.7%) in the oseltamivir phosphate-treated subjects.

**Geriatric Subjects**

The efficacy of oseltamivir phosphate in preventing naturally occurring influenza illness was demonstrated in a randomized, placebo-controlled seasonal prophylaxis trial in elderly residents of skilled nursing homes (aged 65 years or older). Subjects received oseltamivir phosphate capsules 75 mg once daily or placebo taken orally for 42 days during a community outbreak. The incidence of laboratory-confirmed influenza was 3% (7/231) in the placebo group compared to 1% (2/232) in the oseltamivir phosphate group. Subjects received influenza vaccine prior to baseline. The incidence of RT-PCR-confirmed clinical influenza in the placebo group was 3% (7/231) compared to 1% (2/232) in the oseltamivir phosphate group. Approximately 40% of subjects received influenza vaccine prior to baseline. The efficacy parameter was the incidence of laboratory-confirmed influenza defined as meeting all the following criteria (all signs and symptoms must have been present within 24 hours):

- acute temperature greater than or equal to 99.0°F (37.2°C).
- at least one respiratory symptom (cough, nasal secretion, and/or sore throat).
- at least one gastrointestinal symptom (nausea and/or vomiting and/or diarrhea).
- either positive virus isolation or a four-fold increase in virus antibody titers from baseline.

In the post-exposure prophylaxis trial in household contacts of an index influenza case, oseltamivir phosphate capsules 75 mg once daily or placebo taken orally for 42 days. The incidence of laboratory-confirmed influenza was 4% (12/272) in the placebo-treated subjects compared to less than 1% (0.7%) in the oseltamivir phosphate-treated subjects.

In the seasonal (community outbreak) prophylaxis trial in elderly residents of skilled nursing homes, 39% were female (55%), white (79%), non-Hispanic (74%), full term (76%) and infected with influenza A (89%). The efficacy parameter was the incidence of laboratory-confirmed influenza defined as meeting all the following criteria (all signs and symptoms must have been present within 24 hours):

- acute temperature greater than or equal to 99.0°F (37.2°C).
- at least one respiratory symptom (cough, nasal secretion, and/or sore throat).
- at least one gastrointestinal symptom (nausea and/or vomiting and/or diarrhea).
- either positive virus isolation or a four-fold increase in virus antibody titers from baseline.

In the post-exposure prophylaxis trial in household contacts of an index influenza case, oseltamivir phosphate capsules 75 mg once daily or placebo taken orally for 42 days. The incidence of laboratory-confirmed influenza was 4% (12/272) in the placebo-treated subjects compared to less than 1% (0.7%) in the oseltamivir phosphate-treated subjects.

**15.6 Storage and Handling**

Oseltamivir Phosphate Capsules, USP

30 mg capsules: 30 mg free base equivalent of the phosphate salt of the active ingredient (oseltamivir phosphate) in white opaque capsules (NDC 70710-1010-10).

45 mg capsules: 45 mg free base equivalent of the phosphate salt of the active ingredient (oseltamivir phosphate) in light blue opaque capsules (NDC 70710-1009-10).

75 mg capsules: 75 mg free base equivalent of the phosphate salt of the active ingredient (oseltamivir phosphate) in light blue grey opaque capsules (NDC 70710-1009-10).

Store at room temperature for 24 months from the date of manufacture. Store at 25°C (77°F).[1]
Inactive ingredients:  
Active ingredient: oseltamivir phosphate

What are the ingredients in oseltamivir phosphate capsules. For more information, talk with your healthcare provider or pharmacist for information about oseltamivir phosphate capsules that is written for healthcare professionals. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist to explain any terms that you do not understand.

Do not use oseltamivir phosphate capsules for a condition for which it was not prescribed. Do not give oseltamivir phosphate capsules to other people, even if they have the same symptoms you have. It may harm them.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use oseltamivir phosphate capsules for a condition for which it was not prescribed. Do not give oseltamivir phosphate capsules to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist to explain any terms that you do not understand.

It is not known if oseltamivir phosphate capsules are:

• effective in people who are 1 year of age and older, but who have never had a flu symptom; or
• effective in people who have had a flu symptom in the past.

If you take oseltamivir phosphate capsules, tell your healthcare provider right away if you or your child have confusion, speech problems, abnormal movements, agitation, or loss of muscle control. Oseltamivir phosphate can cause serious skin and allergic reactions.

Dose 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 miss a dose after you have taken oseltamivir phosphate capsules, take the missed dose as soon as you remember, except if it is near the next dose. Take your next dose at the usual time. Do not take two doses at the same time.

If oseltamivir phosphate for oral suspension is not available or you cannot swallow oseltamivir phosphate capsules, your healthcare provider or pharmacist may instruct you to use oseltamivir phosphate capsules to start treatment with oseltamivir phosphate capsules and then continue to take oseltamivir phosphate capsules at the usual time.

Tell your healthcare provider about any other conditions you have. Do not use oseltamivir phosphate capsules in patients with end-stage renal disease (ESRD) who are not on dialysis.

Oseltamivir phosphate capsules do not prevent bacterial infections that may happen with the flu. Oseltamivir phosphate capsules are not recommended for people with end-stage renal disease (ESRD) who are not on dialysis.

Keep all medicines out of the reach of children.

Tell your healthcare provider about when you should receive an annual flu vaccination.

Oseltamivir phosphate capsules are not recommended for people with end-stage renal disease (ESRD) who are not on dialysis.

Instruct patients that oseltamivir phosphate capsules are not a substitute for receiving an annual flu vaccination. Talk to your healthcare provider about when you should receive an annual flu vaccination.

Who should not take oseltamivir phosphate capsules?

Do not take oseltamivir phosphate capsules if you are allergic to oseltamivir phosphate or any of the ingredients in oseltamivir phosphate capsules. See the end of this leaflet for a complete list of ingredients in oseltamivir phosphate capsules.

What should I tell my healthcare provider before taking oseltamivir phosphate capsules?

Before you take oseltamivir phosphate capsules, tell your healthcare provider if you:

• have problems swallowing oseltamivir phosphate capsules
• have kidney problems
• have any other medical conditions
• are pregnant or plan to become pregnant. Available information indicates that oseltamivir phosphate capsules do not increase the risk of birth defects
• are breastfeeding or plan to breast-feed. Oseltamivir phosphate capsules can pass into breast milk in small amounts.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacists when you get a new medicine.

How should I take Oseltamivir Phosphate Capsules?

Take oseltamivir phosphate capsules exactly as your healthcare provider tells you. 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 miss a dose after you have taken oseltamivir phosphate capsules, take the missed dose as soon as you remember, except if it is near the next dose. Take your next dose at the usual time. Do not take two doses at the same time.

If oseltamivir phosphate for oral suspension is not available or you cannot swallow oseltamivir phosphate capsules, your healthcare provider or pharmacist may instruct you to use oseltamivir phosphate capsules to start treatment with oseltamivir phosphate capsules and then continue to take oseltamivir phosphate capsules at the usual time.

If your healthcare provider or pharmacist has instructed you to take oseltamivir phosphate for oral suspension or open oseltamivir phosphate capsules, read the detailed Instructions for Use at the end of this leaflet. Ask your pharmacist if you have any questions.

What are the possible side effects of oseltamivir phosphate capsules?

Oseltamivir phosphate capsules may cause serious side effects, including:

• Serious skin and allergy reactions. Oseltamivir phosphate capsules can cause serious skin and allergy reactions. Stop taking oseltamivir phosphate capsules and get medical help right away if you get any of the following symptoms:
  • skin rash or hives
  • your skin is irritated and peels
  • swollen or bruised
  • itching
  • swelling of your face, eyes, lips, tongue, or throat
  • trouble breathing
  • chest pain or tightness
  • change in behavior. People, especially children, who have the flu, can develop nervous system problems and abnormal behavior that can be life-threatening. During treatment with oseltamivir phosphate capsules, tell your healthcare provider right away if you or your child have confusion, speech problems, balance problems, dizziness, disorientation, or unusual or unexplained ideas or thoughts.

The most common side effects of oseltamivir phosphate capsules used for treatment of the flu include nausea, vomiting, and headache.

The most common side effect of oseltamivir phosphate capsules when used for the prevention of the flu include nausea, vomiting, headache, and pain.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of oseltamivir phosphate capsules.

Keep oseltamivir phosphate capsules and all medicines out of the reach of children.

General information about the safe and effective use of Oseltamivir Phosphate Capsules.

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information leaflet. Do not use oseltamivir phosphate capsules for a condition for which it was not prescribed. Do not give oseltamivir phosphate capsules to other people, even if they have the same symptoms you have. It may harm them.

If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about oseltamivir phosphate capsules that is written for health professionals. For more information, contact Zydus Pharmaceuticals at 1-877-953-8779.

What are the ingredients in Oseltamivir Phosphate Capsules?

Active ingredient: oseltamivir phosphate

Inactive ingredients:

Safely throw away any unused oseltamivir phosphate capsules that are out of date or no longer needed.
Oseltamivir phosphate capsules: pregelatinized starch, talc, povidone, croscarmellose sodium, and sodium stearyl fumarate

30mg capsule shell: gelatin, titanium dioxide, and sodium lauryl sulfate

45mg capsules shell: gelatin, titanium dioxide, and sodium lauryl sulfate, FD&C Blue 1, D&C Red 28, and FD&C Red 40

75mg capsules shell: gelatin, titanium dioxide, and sodium lauryl sulfate, FD&C Blue 1, D&C Red 28, and FD&C Red 40

Manufactured by:
Nesher Pharmaceuticals USA LLC.
St. Louis, MO 63134

Distributed by:
Zydus Pharmaceuticals USA Inc.
Pennington, NJ 08534

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised 01/2019

INSTRUCTIONS FOR USE
Oseltamivir phosphate capsules, USP, for oral use (os-el-TAM-ih-veer)

How do I mix the contents of oseltamivir phosphate capsules with sweetened liquids, if directed by my healthcare provider or pharmacist?

You will need:
• the prescribed dose of oseltamivir phosphate capsules
• a small bowl
• sweetened liquid, such as chocolate syrup (regular or sugar-free), corn syrup, caramel topping, or light brown sugar (dissolved in water)

Step 1. Open the contents of the prescribed dose of oseltamivir phosphate capsules into a small bowl.
Step 2. Add a small amount of the sweetened liquid to the capsule contents.
Step 3. Stir the mixture and give the entire dose of oseltamivir phosphate.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Rev. 01/2019

Oselitamivir Phosphate
Capsules, USP

30 mg Carton

Oselitamivir Phosphate
Capsules, USP

45 mg Carton

Oselitamivir Phosphate
Capsules, USP

75 mg Carton

Oseltamivir Phosphate

Product Information

Product Type: HUMAN PRESCRIPTION DRUG

Item Code (Source): NDC:70710-1008

Route of Administration: ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
Strength

OSELTAMIVIR PHOSPHATE (UNII: 4A3O49NGEZ)
OSELTAMIVIR PHOSPHATE (UNII: K6106LV5Q8)
OSELTAMIVIR ACID
30 mg
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## OSELTAMIVIR PHOSPHATE

**Oseltamivir phosphate capsules**

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## OSELTAMIVIR PHOSPHATE

**Oseltamivir phosphate capsules**

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Establishment Name | Address | ID/FEI | Business Operations
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Nesher Pharmaceuticals (USA) LLC | 969028351 | ANALYSIS(70710-1008, 70710-1009, 70710-1010), MANUFACTURE(70710-1008, 70710-1009, 70710-1010) |