

Waveflu Suspension

Product Information: Oseltamivir Phosphate (12mg/ml) Suspension

Composition:

- **Oseltamivir Phosphate:** Each 1 ml of the suspension contains 12 mg of Oseltamivir Phosphate, equivalent to 10.6 mg of Oseltamivir.
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Pharmacological Class:

- **Antiviral Agent:** Neuraminidase inhibitor.
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Indications:

Oseltamivir Phosphate suspension is indicated for the treatment and prevention of influenza (flu) caused by influenza virus types A and B in the following cases:

- **Treatment of acute, uncomplicated influenza** in adults and pediatric patients who have been symptomatic for no more than 48 hours.
 - **Prevention of influenza** in individuals who have been exposed to the virus, particularly in those at high risk of complications, such as the elderly, young children, or individuals with underlying health conditions.
 - **Prophylaxis of influenza** in individuals who are at high risk of contracting the virus and for whom the virus exposure is a concern (e.g., household contact).
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Mechanism of Action:

Oseltamivir is a neuraminidase inhibitor. The influenza virus uses neuraminidase to release new viral particles from infected cells. By inhibiting neuraminidase, Oseltamivir prevents the release of viral particles, thereby limiting the spread of the virus within the body. This reduces the severity and duration of influenza symptoms and prevents the virus from spreading to others.

Dosage and Administration:

- **For treatment of influenza:**
 - **Adults and adolescents (13 years and older):** 75 mg (6.25 ml) twice daily for 5 days.
 - **Children (1 year and older):**
 - **Dosing depends on the child's weight and age.** For children weighing 15-23 kg, the dose is 30 mg (2.5 ml) twice daily for 5 days.
 - **For children weighing 23-40 kg,** the dose is 45 mg (3.75 ml) twice daily for 5 days.
 - **For children weighing 40 kg or more,** the dose is 75 mg (6.25 ml) twice daily for 5 days.
- **For prevention of influenza:**
 - **Adults and adolescents (13 years and older):** 75 mg (6.25 ml) once daily for at least 10 days following exposure.
 - **Children (1 year and older):** Dosing is based on weight, typically for 10 days following exposure.

- Children weighing 15-23 kg: 30 mg (2.5 ml) once daily.
 - Children weighing 23-40 kg: 45 mg (3.75 ml) once daily.
 - Children weighing 40 kg or more: 75 mg (6.25 ml) once daily.
 - For infants under 1 year: The use of Oseltamivir in children under 1 year should be done under strict medical supervision, with adjusted dosing based on weight.
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Contraindications:

- Hypersensitivity to Oseltamivir or any component of the formulation.
 - Severe renal impairment ($\text{CrCl} < 10 \text{ mL/min}$) without adjustment of dose.
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Warnings and Precautions:

- **Renal impairment:** Dose adjustment is necessary in patients with moderate renal impairment ($\text{CrCl} 10\text{--}30 \text{ mL/min}$).
- **Neuropsychiatric effects:** There have been reports of neuropsychiatric events (including hallucinations, delirium, and self-harm) in pediatric patients taking Oseltamivir. Monitor for any signs of behavioral changes, particularly in children, and discontinue therapy if necessary.
- **Not a substitute for the flu vaccine:** Oseltamivir is not a substitute for vaccination. It is used for the treatment or prevention of influenza after infection has occurred, not for preventing initial infection.
- **Pregnancy and breastfeeding:** Use Oseltamivir only when the potential benefits outweigh the risks. Limited data are available on its use during

pregnancy, but it is considered safe for use if prescribed by a healthcare provider. It is excreted in breast milk, so nursing mothers should use Oseltamivir with caution.

Adverse Effects:

- **Common:**
 - Nausea, vomiting, abdominal pain.
 - Headache, fatigue, and dizziness.
 - Insomnia and mild respiratory symptoms.
- **Serious:**
 - Neuropsychiatric events (e.g., confusion, hallucinations, self-harm, especially in pediatric patients).
 - Allergic reactions, including anaphylaxis.
 - Severe skin reactions, including erythema multiforme and toxic epidermal necrolysis.

In case of any serious side effects, immediate medical attention is advised.

Drug Interactions:

- **Live attenuated influenza vaccine (LAIV):** Oseltamivir may reduce the effectiveness of the LAIV if given simultaneously. Allow a minimum of 2 weeks between LAIV administration and Oseltamivir treatment.
- **Probenecid:** Probenecid can increase the plasma concentration of Oseltamivir by inhibiting its renal elimination. This may require dose adjustment.
- **Antacids:** Taking antacids containing aluminum or magnesium within 2 hours of Oseltamivir administration may reduce the absorption of Oseltamivir. It

is recommended to separate their use by at least 2 hours.

Use in Special Populations:

- **Pregnancy:** Category C. Oseltamivir should be used during pregnancy only if the potential benefit justifies the risk to the fetus.
 - **Lactation:** Oseltamivir is excreted in human milk in low amounts. Use with caution during breastfeeding, particularly when nursing a newborn or premature infant.
 - **Geriatric Use:** Oseltamivir can be used in elderly patients, but the dose should be adjusted in cases of renal impairment.
 - **Pediatric Use:** Safe and effective in children aged 1 year and older when used for the treatment or prevention of influenza. Safety and efficacy in children younger than 1 year have not been established.
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Storage:

- Store the suspension in the original container at 15–30°C (59–86°F).
 - Keep the bottle tightly closed to avoid contamination.
 - Do not freeze.
 - After reconstitution, the suspension can be stored at room temperature for up to 17 days. Discard unused medicine after this time.
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Packaging:

- Available in 75mL bottles of Oseltamivir Phosphate suspension (12 mg/mL).

- Includes a calibrated oral dosing syringe or cup for accurate dosing.
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Patient Instructions:

1. Shake the bottle well before each use to ensure the suspension is well-mixed.
 2. Use the provided dosing syringe or cup to measure the exact dose. Do not exceed the prescribed dose.
 3. Oseltamivir should be taken with or without food. If you experience nausea, it may help to take it with food.
 4. Complete the full course of treatment even if symptoms improve, to ensure the infection is fully treated.
 5. If you miss a dose, take it as soon as you remember unless it is almost time for the next dose. Do not take two doses at once to make up for a missed dose.
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Oseltamivir Phosphate (12mg/ml) Suspension is a highly effective antiviral treatment for the flu. It is particularly useful when administered within 48 hours of the onset of flu symptoms and is equally effective as a preventive measure in individuals who have been exposed to the virus. Always use it as directed by a healthcare professional to ensure the best outcome and minimize the risk of side effects.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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