

Oseltamivir Phosphate Cas No. 204255-11-8

Oseltamivir is a neuraminidase inhibitor, serving as a competitive inhibitor towards sialic acid, found on the surface proteins of normal host cells. By blocking the activity of the neuraminidase, Oseltamivir prevents new viral particles from being released by infected cells.

Active Pharmaceuticals Ingredients Manufacturers



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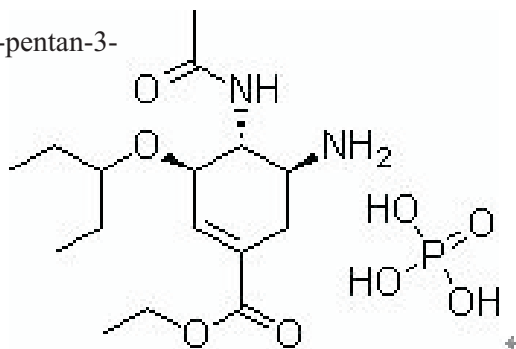
Taj Pharmaceuticals Ltd.**Oseltamivir Phosphate
CAS No. : 204255-11-8****Product name:** Oseltamivir phosphate

Chemical name: Ethyl(3R,4R,5S)-4-acetamido-5-amino-3-pentan-3-ylloxycyclohexene-1-carboxylate phosphate

CAS No.: 204255-11-8

Molecular formula : C₁₆H₂₈N₂O₄.H₃PO₄

Assay: 97%min

**Product Description**

Appearance: White to off-white crystalline powder

Purity(HPLC): 99%min

Melting Point : 201-203degree

Optical Rotation: -34.0- -38.0degree

Moisture: 0.30%max

Heavy metals: 20ppm max

Residue on ignition: 0.1%max

Impurity Ro-1637: 0.03%max

Any other individual impurity: 0.50%max

Total impurities: 1.0%max

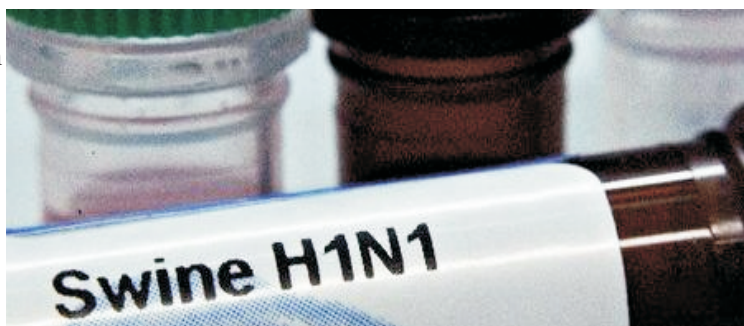
Productivity: 500kg/month

Mode of action

Oseltamivir is a neuraminidase inhibitor, serving as a competitive inhibitor towards sialic acid, found on the surface proteins of normal host cells. By blocking the activity of the neuraminidase, Oseltamivir prevents new viral particles from being released by infected cells.

**Resistance**

As with other antivirals, resistance to the agent was expected with widespread use of oseltamivir, though the emergence of resistant viruses was expected to be less frequent than with amantadine or rimantadine. The resistance rate reported during clinical trials up to July 2004 was 0.33% in adults, 4.0% in children, and 1.26% overall. Mutations conferring resistance are single amino acid residue substitutions in the neuraminidase enzyme. H3N2 Mutant H3N2 influenza A virus isolates



resistant to oseltamivir were found in 18% of a group of 50 Japanese children treated with oseltamivir. This rate was similar to another study where resistant isolates of H1N1 influenza virus were found in 16.3% of another cohort of Japanese children. Several explanations were proposed by the authors of the studies for the higher-than-expected resistance rate detected. First, children typically have a longer infection period, giving a longer time for resistance to develop. Second, Kiso et al. claim to have used more rigorous detection techniques than previous studies.



Taj Group of Companies

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Oseltamivir Phosphate

Formula C₁₆H₂₈N₂O₄.H₃PO₄

Cas No. **204255-11-8**



H5N1 avian influenza

High-level resistance has been detected in one girl suffering from H5N1 avian influenza in Vietnam. She was being treated with oseltamivir at time of detection. de Jong et al. (2005) describe resistance development in two more Vietnamese patients suffering from H5N1, and compare their cases with six others. They suggest that the emergence of a resistant strain may be associated with a patient's clinical deterioration. They also note that the recommended dosage of oseltamivir does not always completely suppress viral replication, a situation that could favor the emergence of resistant strains. Moscona (2005) gives a good overview of the resistance issue, and says that personal stockpiles of Tamiflu could lead to under-dosage and thus the emergence of resistant strains of H5N1.

Resistance is of concern in the scenario of an influenza pandemic (Wong and Yuen 2005), and may be more likely to develop in avian influenza than seasonal influenza due to the potentially longer duration of infection by novel viruses. Kiso et al. suggest that "a higher prevalence of resistant viruses should be expected" during a pandemic.

Article : Swine influenza

Swine influenza (also called H1N1 flu, swine flu, hog flu, and pig flu) is an infection by any one of several types of swine influenza virus. Swine influenza virus (SIV) is any strain of the influenza family of viruses that is endemic in pigs. As of 2009, the known SIV strains include influenza C and the subtypes of influenza A known as H1N1, H1N2, H3N1, H3N2, and H2N3.

Swine influenza virus is common throughout pig populations worldwide. Transmission of the virus from pigs to humans is not common and does not always lead to human influenza, often resulting only in the production of antibodies in the blood. If transmission does cause human influenza, it is called zoonotic swine flu. People with regular exposure to pigs are at increased risk of swine flu infection. The meat of an infected animal poses no risk of infection when properly cooked.

During the mid-20th century, identification of influenza subtypes became possible, allowing accurate diagnosis of transmission to humans. Since then, only 50 such transmissions have been confirmed. These strains of swine flu rarely pass from human to human. Symptoms of zoonotic swine flu in humans are similar to those of influenza and of influenza-like illness in general, namely chills, fever, sore throat, muscle pains, severe headache, coughing, weakness and general discomfort.





Note: Veterinary use

There have been anecdotal reports of oseltamivir reducing disease severity and hospitalization time in canine parvovirus infection. The drug may limit the ability of the virus to invade the crypt cells of the small intestine and decrease gastrointestinal bacteria colonization and toxin production.



This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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