

Oseflu®

Oseltamivir
Capsule

Description

Oseltamivir is an ethyl ester prodrug requiring ester hydrolysis for conversion to the active form, Oseltamivir carboxylate. The proposed mechanism of action of oseltamivir is inhibition of influenza virus neuraminidase with the possibility of alteration of virus particle aggregation and release.

Indications

Oseltamivir is indicated for prevention of flu (influenza) in adults and adolescents aged 13 years and over who have been in contact with someone diagnosed with flu; treatment of flu (influenza) in adults and in children over one year of age when the influenza virus is circulating in the community.

Dosage and Administration

Oseltamivir Phosphate may be taken with or without food. However, when taken with food, tolerability may be enhanced in some patients.

Standard Dosage – Treatment of Influenza:

Adults and Adolescents: The recommended oral dose of Oseltamivir for treatment of influenza in adults and adolescents 13 years and older is 75 mg twice daily for 5 days. Treatment should begin within 2 days of onset of symptoms of influenza.

Standard Dosage – Prophylaxis of Influenza

The safety and efficacy of Oseltamivir for prophylaxis of influenza in pediatric patients younger than 13 years of age have not been established.

The recommended oral dose of Oseltamivir for prophylaxis of influenza in adults and adolescents 13 years and older following close contact with an infected individual is 75 mg once daily for at least 7 days. Therapy

should begin within 2 days of exposure. The recommended dose for prophylaxis during a community outbreak of influenza is 75 mg once daily. Safety and efficacy have been demonstrated for up to 6 weeks. The duration of protection lasts for as long as dosing is continued.

Contraindications

This product is contraindicated in patients with known hypersensitivity to any of the components of the product.

Warning

No information available.

Precaution

General

There is no evidence for efficacy of Oseltamivir Phosphate in any illness caused by agents other than influenza viruses Types A and B.

Efficacy of Oseltamivir Phosphate in patients who begin treatment after 40 hours of symptoms has not been established.

Hepatic Impairment

The safety and pharmacokinetics in patients with hepatic impairment have not been evaluated.

Renal Impairment

Dose adjustment is recommended for patients with a serum creatinine clearance <30 mL/min.

High Risk Group

Pregnancy

Pregnancy Category C: There are insufficient human data upon which to base an evaluation of risk of Oseltamivir Phosphate to the pregnant woman or developing fetus.

Nursing Mothers

It is not known whether oseltamivir or oseltamivir carboxylate is excreted in human milk. Oseltamivir Phosphate should, therefore, be used only if the potential benefit for the lactating mother justifies the potential risk to the breast-fed infant.

Geriatric Use

The safety of Oseltamivir Phosphate has been established in clinical studies.

Pediatric Use

The safety and efficacy of Oseltamivir Phosphate in pediatric patients younger than 1 year of age have not been studied. Oseltamivir Phosphate is not indicated for either treatment or prophylaxis of influenza in pediatric patients younger than 1 year of age.

Side Effect

The most frequently reported adverse events are nausea and vomiting. These events generally of mild to moderate degree and usually are occurred on the first 2 days of administration. Additional adverse events occurring in <1% of patients receiving Oseltamivir for treatment include unstable angina, anemia, pseudomembranous colitis, humerus fracture, pneumonia, pyrexia, and peritonsillar abscess.

Drug Interaction

Information derived from pharmacology and pharmacokinetic studies of Oseltamivir suggests that clinically significant drug interactions are unlikely.

Co-administration with amoxicillin does not alter plasma levels of either compound.

Storage

Store at 25°C. Keep out of reach of children.

Commercial Pack

Oseflu® capsule: Box containing 10 capsules in blister strip. Each capsule contains Oseltamivir Phosphate INN equivalent to Oseltamivir 75 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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