HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use

RESTOLAR safely and effectively. See full prescribing information for

RESTOLAR.

RESTOLAR®

(oseltamivir phosphate) capsules, for oral use

RESTOLAR®

(oseltamivir phosphate) for oral suspension

Initial U.S. Approval: 1999

--------------------------- RECENT MAJOR CHANGES ---------------------------

Indications and Usage (1.1) 12/2012

Dosage and Administration (2.1, 2.2, 2.3, 2.4. 2.8) 12/2012

Warnings and Precautions (5.4) 12/2012

--------------------------- INDICATIONS AND USAGE ----------------------------

RESTOLAR is an influenza neuraminidase inhibitor indicated for:

 Treatment of acute, uncomplicated influenza in patients 2 weeks of age

and older who have been symptomatic for no more than 2 days. (1.1)

 Prophylaxis of influenza in patients 1 year and older. (1.2)

Important Limitations of Use:

 Efficacy not established in patients who begin therapy after 48 hours of

symptoms. (1.3)

 Not a substitute for annual influenza vaccination. (1.3)

 No evidence of efficacy for illness from agents other than influenza viruses

types A and B. (1.3)

 Consider available information on influenza drug susceptibility patterns

and treatment effects when deciding whether to use. (1.3)

----------------------- DOSAGE AND ADMINISTRATION -----------------------

Treatment of influenza (2.2)

 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: 3mg/kg twice daily

for 5 days.

 Renally impaired adult patients (creatinine clearance 10-30 mL/min):

Reduce to 75 mg once daily for 5 days (2.4)

Prophylaxis of influenza (2.3)

 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

 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 6 weeks

 Renally impaired adult patients (creatinine clearance 10-30 mL/min):

Reduce to 75 mg once every other day or 30 mg once daily (2.4)

--------------------- DOSAGE FORMS AND STRENGTHS ---------------------

 Capsules: 30 mg, 45 mg, 75 mg (3)

 Powder for oral suspension: 360 mg oseltamivir base (constituted to a final

concentration of 6 mg/mL) (3)

------------------------------ CONTRAINDICATIONS ------------------------------

Patients with known serious hypersensitivity to oseltamivir or any of the

components of RESTOLAR (4)

----------------------- WARNINGS AND PRECAUTIONS -----------------------

 Serious skin/hypersensitivity reactions such as Stevens-Johnson

Syndrome, toxic epidermal necrolysis and erythema multiforme:

Discontinue RESTOLAR and initiate appropriate treatment if allergic-like

reactions occur or are suspected. (5.1)

 Neuropsychiatric events: Patients with influenza, including those receiving

RESTOLAR, particularly pediatric patients, may be at an increased risk of

confusion or abnormal behavior early in their illness. Monitor for signs of

abnormal behavior. (5.2)

------------------------------ ADVERSE REACTIONS ------------------------------

Most common adverse reactions (>1% and more common than with placebo):

 Treatment studies – Nausea, vomiting (6.1)

 Prophylaxis studies – Nausea, vomiting, diarrhea, abdominal pain (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at

1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

------------------------------ DRUG INTERACTIONS-------------------------------

Live attenuated influenza vaccine, intranasal (7):

 Do not administer until 48 hours following cessation of RESTOLAR.

 Do not administer RESTOLAR until 2 weeks following administration of

the live attenuated influenza vaccine, unless medically indicated.

----------------------- USE IN SPECIFIC POPULATIONS -----------------------

 Pregnancy: No data in pregnant women. Use only if clearly needed. (8.1)

 Nursing mothers: Caution should be exercised when administered to a

nursing woman. (8.3).

See 17 for PATIENT COUNSELING INFORMATION and FDAapproved patient labeling

Revised: 12/2012