Oseltamivir phosphate capsules are not a substitute for early influenza vaccination on an annual basis as recommended by public health authorities. Recommended Treatment Regimen:

**30 mg once daily**
- **oseltamivir phosphate**
- **10 capsules (30 mg)**

At room temperature (25°C/77°F).

For patients less than 1 year of age, provide an appropriate dosing device that can accurately measure and administer small doses. It is not known if oseltamivir phosphate capsules are:

- •...immune systems (immunocompromised)
- •...vaccination.

Talk to your healthcare provider about when you should receive an annual influenza vaccination.

**Recommended Dosage**

<table>
<thead>
<tr>
<th>Treatment/Course</th>
<th>Dosage</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of influenza</td>
<td>30 mg once daily</td>
<td>For adults with an estimated creatinine clearance less than or equal to 60 mL per minute and for patients less than 1 year of age.</td>
</tr>
</tbody>
</table>

**Dosage Modifications**

- Renally impaired adult patients (creatinine clearance >30 to 60 mL/min): Reduce to 30 mg twice daily for 5 days (2.4).
- Renally impaired adult patients (creatinine clearance >10 to 30 mL/min): Reduce to 30 mg once daily for 5 days (2.4).

**Duration of Protection**

- Seasonal (prophylaxis): Up to 6 weeks (or up to 12 weeks in immunocompromised patients) (1.3).
- Post-exposure prophylaxis of influenza: 5 to 14 days (2.4).

**Product Exposures**

- Oral exposure: Rabbits (≥8 times human exposures). In rats and mice, embryo-fetal effects consisting of an increased incidence of stillbirths and neonatal deaths has been observed (17).

**Safety in Specific Populations**

- Pregnancy (8.4).
- Breastfeeding (8.5).
- Children (2.2). The effectiveness of oseltamivir phosphate capsules is not recommended for people with end-stage renal disease (ESRD) requiring hemodialysis (8.6).

**Adverse Events**

- **Respiratory System Disorders**: Upper respiratory tract infections (URTI) and bronchitis have been reported as adverse events with oseltamivir phosphate capsules.
- **Gastrointestinal System Disorders**: Nausea, vomiting, and abdominal pain were reported.
- **Nervous System Disorders**: Delirium and abnormal behavior (5.2).

**Clinical Trials Experience**

In controlled clinical trials, the most commonly reported adverse events in patients treated with oseltamivir phosphate capsules were: nausea (42%), vomiting (35%), and diarrhea (31%).

Closely monitor oseltamivir phosphate-treated patients with influenza for signs of secondary bacterial infections and treat them as appropriate (6.1). There have been postmarketing reports of delirium and abnormal behavior that can lead to death (5.2).

Nervous system problems and abnormal behavior that can lead to death. During treatment and prophylaxis, oseltamivir capsules should be used carefully in elderly patients because of the increased risk of adverse reactions including delirium and abnormal behavior.

**Dosage in Patients with Renal Impairment**

- Renally impaired adult patients (creatinine clearance >10 to 30 mL/min): Reduce to 30 mg once daily for 5 days (2.4).

**Risk of Bacterial Infections**

Closely monitor oseltamivir phosphate-treated patients with influenza for signs of secondary bacterial infections and treat them as appropriate (5.3).

**Neuropsychiatric Events**

There have been postmarketing reports of delirium and abnormal behavior that can lead to death. During treatment and prophylaxis, oseltamivir capsules should be used carefully in elderly patients because of the increased risk of adverse reactions including delirium and abnormal behavior (5.2).

**Drug Interactions**

- **Co-administration of Inhibitors or Inducers of CYP2C19**: Inducers or inhibitors of CYP2C19 may increase or decrease the exposure to oseltamivir carboxylate.
- **Co-administration of Other Drugs**: Coadministration of oseltamivir may affect the metabolism or toxicity of other drugs that are primarily eliminated by hepatic metabolism.

**Dosage Forms and Administration**

- **Capsule**: Black and yellow color combination with black colour band, imprinted with “M" and light yellow opaque colour cap imprinted with “75 mg".

**Packaging Information**

- Open Dimension: 210 x 360 x 2 mm
- Mode of supply: Bundles of 25's, 50's & 100's
- Pharma Code: 63090000
- Font Type: Arial

**Warning**

Read the full Prescribing Information before dispensing this medication. The full prescribing information is available at oseltamivir.com. Avoid exposure to live influenza virus while using oseltamivir phosphate capsules.
Adolescent Use

13 to 17 years of age: Safety and efficacy in adolescent patients 13 to 17 years of age was supported by adequate and
464
either a positive virus isolation or a four-fold or greater increase in virus antibody titers from baseline or at illness visits.
reduced susceptibility to
75 mg once daily
477
at least one respiratory symptom (cough, sore throat, nasal congestion),
years (median age 5
112x1986
60 mm
156x1184
Mechanism of Action

12.1 Mechanism of Action

Follows:

Oseltamivir carboxylate is the active metabolite of oseltamivir phosphate, the inactive prodrug that is rapidly and almost completely

and 6069 ng·h/mL under fed conditions) of oseltamivir carboxylate.

Recommended Treatment Regimens

Step 2. Add a small amount of the sweetened liquid to the capsule contents.

Reactions (6.1) and Use in Specific Populations (8.4)

•

[see Dosage and Administration (2.4)].

[see Indications and Usage (1.3), and Use in Specific Populations (8.6)

Absorption and

Recommended Treatment Regimens

Step 2. Add a small amount of the sweetened liquid to the capsule contents.

Prescription

[see Indications and Usage (1.3), and Use in Specific Populations (8.6)

Vaccines

[see Indications and Usage (1.3), and Use in Specific Populations (8.6)

Listed Above

[see Indications and Usage (1.3), and Use in Specific Populations (8.6)

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