Monograph	
Oseltamivir Monograph - Paediatric	
Scope (Staff):	Clinical Staff – Medical, Nursing, Pharmacy
Scope (Area):	Clinical Staff – Medical, Nursing, Pharmacy

This document should be read in conjunction with this DISCLAIMER

DESCRIPTION	Oseltamivir is a neuraminidase inhibitor. It reduces influenza virus replication by inhibiting the viral surface enzyme neuraminidase thereby preventing release of new virus from cells.(1-3) Oseltamivir is indicated in the treatment of Influenza A and B virus infection, and for prophylaxis in high risk patients of influenza commenced within 48 hours of close contact with an infected person.(1, 3) The use of oseltamivir as prophylaxis for influenza is NOT a substitute for influenza vaccine.(2)
INDICATIONS AND RESTRICTIONS	**IV and Oral: Monitored (orange) antiviral** Where use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient). The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications. If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.
CONTRAINDICATIONS	Oseltamivir is contraindicated in patients with a previous hypersensitivity reaction to oseltamivir or other neuraminidase inhibitor.(2, 4)
PRECAUTIONS	There have been rare reports of neuropsychiatric side effects, mainly in children with influenza A or B using oseltamivir. These include episodes of abnormal behaviour, hallucinations, delirium and self-harm.(1) Hereditary fructose intolerance as the old liquid (Tamiflu®) contains 0.9g of sorbitol for every 30mg of oseltamivir.(1, 2, 4)
FORMULATIONS	**Available at PMH:** 6mg/mL oral suspension for reconstitution (Tamiflu®) 75mg oral capsules (Tamiflu®) **Other preparations available:** 30mg and 45mg oral capsules (Tamiflu®)
DOSAGE	The doses listed below fall within the standard range. Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.

Treatment and post exposure prophylaxis should commence within 48 hours of symptoms beginning or close contact with an infected person.(2)

Neonates:
Please refer to neonatal clinical care drug protocols

Oral:
Treatment dose: 3mg/kg/dose (to a maximum of 75mg) twice daily for 5 days.(4-6) (See suggested dose bands below.)

Post exposure prophylaxis: 3mg/kg/dose (to a maximum of 75mg) once daily for 10 days.(4-6) (See suggested dose bands below.)
There is limited data regarding the use of oseltamivir for prophylaxis in patients under 1 year of age. It should only be used in high risk infants and in consultation with an infectious diseases consultant.
Post exposure prophylaxis is NOT a replacement for influenza vaccination.(1)

During an epidemic, post exposure prophylaxis can be extended to up to 6 weeks in immunocompetent patients and up to 12 weeks in immunocompromised patients on the advice of infectious diseases or clinical microbiology consultants.

Weight	Dose	Treatment	Prophylaxis
≤1 year	3mg/kg/dose	Twice daily for 5 days	ONCE daily for 10 days
>1year and ≤15kg	30mg		
>1year and >15kg – 23kg	45mg		
>1year and >23kg – 40kg	60mg		
>1year and >40kg	75mg		

DOSAGE ADJUSTMENT

Dosage adjustment required in renal impairment:
Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 60mL/min).(1)
To calculate the estimated glomerular filtration rate (eGFR) use the following formula:

$$eGFR\ (mL/min/1.73m^2) = \frac{36.5 \times height\ (in\ cm)}{Serum\ creatinine\ (micromol/L)}$$

Treatment doses(3, 6)	
CrCl	**Dose adjustment**
≥60mL/minute	Normal dosing
≥30 to <60mL/minute	40% of the normal dose given twice daily
≥10 to <30mL/minute	40% of the normal dose given once daily
<10mL/minute	Avoid

<table>
<tr><td></td><td>
<table>
<tr><th colspan="2">Prophylaxis doses(3, 6)</th></tr>
<tr><td>≥60mL/minute</td><td>Normal dosing</td></tr>
<tr><td>≥30 to <60mL/minute</td><td>40% of the normal dose given once daily</td></tr>
<tr><td>≥10 to <30mL/minute</td><td>40% of the normal dose given every 48 hours</td></tr>
<tr><td><10mL/minute</td><td>Avoid</td></tr>
</table>

Dosage adjustment required in hepatic impairment:
No dosage adjustment is required for mild to moderate hepatic impairment (Child-Pugh score ≤9). Contact Pharmacy in cases of severe hepatic impairment.(4, 7)</td></tr>
<tr><td>RECONSTITUTION</td><td>To reconstitute the proprietary 6mg/mL oral suspension (Tamiflu®):
Tap the closed bottle several times to loosen the powder, add 55mL of purified water to the powder and shake well for 15 seconds. This suspension can be kept for 10 days at <25˚C OR 17 days if stored between 2 and 8˚C.(4)

If the proprietary oral suspension is unavailable and a portion of a capsule is required:
Open the 75mg capsule and mix with 5mL of purified water. This will create a 15mg/mL solution. Draw up the required dose and mix with a teaspoon of sweetened food product (for example chocolate sauce or jam). This mixture must be taken immediately. Ensure that the full dose is administered.(4)</td></tr>
<tr><td>ADMINISTRATION</td><td>Oseltamivir may be taken with or without food, although administering it with food may improve tolerability. It is extremely bitter. To make it more palatable, it may be mixed with a sweetened food product (such as chocolate syrup) or soft food and administered immediately.(1, 2, 4)

Shake the suspension well before measuring out the required dose.(4)</td></tr>
<tr><td>MONITORING</td><td>Patients and carers should monitor for neuropsychiatric symptoms (e.g. abnormal behaviour, hallucinations, delirium etc.) throughout treatment.(1, 2)

Patients should also be monitored for fevers and symptomatic improvement as well as renal function.(2, 8)

Diabetic patients who are prescribed the liquid formulation should also check their blood glucose levels more frequently due to the sucrose content of the suspension.(2)</td></tr>
<tr><td>ADVERSE EFFECTS</td><td>Common: nausea, vomiting (usually for first 1–2 days), diarrhoea, abdominal pain, dyspepsia, headache.(1, 6)

Rare: Neuropsychiatric symptoms, mainly in children (e.g. abnormal behaviour, hallucinations, delirium), GI bleeding, arrhythmias, convulsions, hypothermia, insomnia, vertigo, haemorrhagic colitis, hepatitis and increased liver enzymes in patients with influenza-like illness, rash, eczema, allergic reactions including anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytopenia, visual disturbances, conjunctivitis.(1, 2, 6)</td></tr>
</table>

COMPATIBLE FLUIDS	Not applicable
STORAGE	**Capsules:** Store below 25˚C **Suspension:** Store the dry powder prior to reconstitution below 25˚C, after reconstitution, the suspension may be stored for 10 days at < 25˚C OR for 17 days between 2-8 ˚C.(4) During a pandemic additional storage requirements (e.g. treatment as a Schedule 4 recordable medication may be implemented)
INTERACTIONS	**Oseltamivir has few drug interactions; please consult PMH approved references, your ward pharmacist or Pharmacy on extension 8703 for more information** • Probenecid may increase the levels of oseltamivir, there is limited information regarding any dosage adjustments required.(2)
COMMENTS	When used for treatment, oseltamivir is intended to shorten the duration of symptoms such as fever, headache, sore muscles, cough and sore throat. If used as post-exposure prophylaxis, there is still the potential to get influenza when taking oseltamivir.(1) Oseltamivir is not recommended for the routine prevention against influenza. Annual influenza vaccination is recommended to prevent infection.(1) The oral suspension contains 0.9grams of sorbitol for every 30mg of oseltamivir.(1, 4)
MANUFACTURER SAFETY DATA SHEET (SDS)	To access to the Manufacturer SDS for this product, use the following link to ChemAlert.

Please note: The information contained in this guideline is to assist with the preparation and administration of **oseltamivir.** Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related policy, procedures and guidelines.
Antimicrobial Stewardship Policy

Resources
ChAMP Empiric Guidelines

References

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8. Micromedex 2.0 [Internet]. Truven Health Analytics. 2016 [cited 12/10/2016].

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