MONOGRAPH

Oseltamivir Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments | Administration | Compatibility | Monitoring

DRUG CLASS

Oseltamivir is a neuraminidase inhibitor.[1-3]

INDICATIONS AND RESTRICTIONS

- Oseltamivir is indicated in the treatment of Influenza A and B virus infection, and for prophylaxis in patients at high risk of severe influenza or complications, commenced within 48 hours of close contact with an infected person.[1, 3-5]
- The use of oseltamivir as prophylaxis for influenza is NOT a substitute for influenza vaccine.[3, 5, 6]

Oral: Monitored (orange) antiviral

- If the 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

- Hypersensitivity to oseltamivir or any component of the formulation.[2, 5]

PRECAUTIONS

- There have been rare reports of neuropsychiatric side effects, mainly in children with influenza A or B using oseltamivir.[1-3, 5, 7] These include episodes of abnormal behaviour, hallucinations, delirium and self-harm.[1-3, 5, 7]
    - *Note:* direct causation by oseltamivir has not been established as influenza infection can cause neuropsychiatric symptoms.[1-3, 5]
- Hereditary fructose intolerance: oseltamivir powder for oral suspension (Tamiflu®) contains 0.9 g of sorbitol for every 30 mg of oseltamivir.[1, 5]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 6 mg/mL oral suspension for reconstitution
- 75 mg oral capsules
- 30 mg oral capsules

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Dosing in Overweight and Obese Children: Dose based on measured body weight.[2]

- Treatment and post-exposure prophylaxis should commence within 48 hours of symptoms beginning or close contact with an infected person.[1-4] In patients with severe influenza, later treatment (within 4 days) is still of benefit.[1, 3]
- The use of oseltamivir as prophylaxis for influenza is NOT a substitute for influenza vaccine.[3, 5, 6]

Oral:

Recommended dosing regimen of oseltamivir: [1-5, 8]

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

- 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.
- During an epidemic, post-exposure prophylaxis can be extended to up to 6 weeks in immunocompetent patients[1, 3, 8] and up to 12 weeks in immunocompromised patients[5, 8] on the advice of Infectious Diseases or Clinical Microbiology Consultants.

Renal impairment:

- eGFR calculator

Treatment doses[8]	
eGFR	*Dose adjustment*
≥ 60 mL/minute	Normal dosing
≥ 30 to < 60 mL/minute	40% of the normal dose given twice daily
≥ 10 to < 30mL/minute	40% of the normal dose given ONCE daily
< 10 mL/minute	Oseltamivir not recommended
Prophylaxis doses[8]	
≥ 60 mL/minute	Normal dosing
≥ 30 to < 60 mL/minute	40% of the normal dose given ONCE daily
≥ 10 to < 30 mL/minute	40% of the normal dose given every 48 hours
< 10 mL/minute	Oseltamivir not recommended

Hepatic impairment:

- No dosage adjustment is required for mild to moderate hepatic impairment (Child-Pugh score ≤ 9).[2, 3, 5]
- Safety and pharmacokinetics have not been established for patients with severe hepatic impairment.[3]

RECONSTITUTION & ADMINISTRATION

To reconstitute the proprietary 6 mg/mL oral suspension:

- Tap the closed bottle several times to loosen the powder, add the volume of purified water according to the manufacturer's instruction to the powder and shake well for 15 seconds.[5]

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 until an even dispersion is formed. This will create a 15mg/mL solution. [5]
- Draw up the required dose immediately (discarding unused suspension) and mix with a

teaspoon of sweetened food product (for example chocolate sauce, yoghurt or apple puree; to disguise the bitter taste). Give immediately after mixing.[5]

Administration

- Oseltamivir may be taken with or without food, although administering it with food may improve tolerability.[1, 2, 5]
- 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, 5]
- Shake the suspension well before measuring out the required dose.[2, 3, 5]

MONITORING

- Patients and carers should monitor for neuropsychiatric symptoms (e.g. abnormal behaviour, hallucinations, delirium etc.) throughout treatment.[1-3, 5, 7] There are rare case reports of self-injury, delirium and abnormal behaviour in children taking oseltamivir to treat influenza.[1-3, 5, 7]
- Patients should also be monitored for symptomatic improvement as well as renal function.[2, 7]

ADVERSE EFFECTS

Common: nausea, vomiting (usually for first 1–2 days), diarrhoea, abdominal pain, dyspepsia, headache, dizziness.[1-3, 8]Gastrointestinal adverse effects may be improved by giving oseltamivir with food[1-3]

Infrequent: arrhythmias, convulsions, skin reactions[8]

Rare: neuropsychiatric symptoms (mainly in children; e.g. abnormal behavior, hallucinations, delirium), haemorrhagic colitis, hepatitis and abnormal liver enzymes, eczema, allergic reactions including anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrolysis, thrombocytopenia, visual disturbances, conjunctivitis.[1, 2, 8]

STORAGE

Capsules: Store below 25˚C.[5]

Suspension: Store the dry powder prior to reconstitution below 25˚C.[5] After reconstitution, suspension may be stored below 25˚C for up to 10 days; or refrigerated (2-8˚C) for up to 17 days.[5]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

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 CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

References

1. Australian Medicines Handbook. Oseltamivir [Internet]. Adelaide (SA): Australian Medicines Handbook Pty Ltd.; 2022 [cited 2022 Nov 02]. Available from: Australian Medicines Handbook.
2. Lexicomp Editorial Advisory Panel. Oseltamivir: drug information [Internet]. Waltham (MA): Lexicomp Inc.; 2022 [cited 2022 Nov 02]. Available from: UpToDate.
3. Oseltamivir pediatric monograph [Internet]. Philadelphia (PA): Elsevier Inc.; 2019 [cited 2022 Nov 03]. Available from: Clinical Pharmacology powered by ClinicalKey.
4. Influenza [Internet]. Melbourne (VIC): Therapeutic Guidelines Ltd; 2019 [cited 2022 Nov 03]. Available from: eTherapeutic Guidelines.
5. Tamiflu [full product information] [Internet]. Crows Nest (NSW): MIMS Australia Pty Ltd.; 2021 [cited 2022 Nov 03; last updated 2021 Jun 01]. Available from: MIMS Online.
6. Neuraminidase inhibitors [Internet]. Adelaide (SA): Australian Medicines Handbook Pty Ltd.; 2022 [cited 2022 Nov 02]. Available from: Australian Medicines Handbook.
7. Oseltamivir [Internet]. Michigan: Truven Health Analytics; 2022 [cited 2022 Nov 21]. Available from: Micromedex.
8. Paediatric Formulary Committee. Oseltamivir [Internet]. London: Royal Pharmaceutical Society and RCPCH Publications Ltd.; 2021 [cited 2022 Nov 02]. Available from: BNF for Children.

This document can be made available in alternative formats on request for a person with a disability.

File Path:	W:\Paediatrics\PMH\ChAMP\Monographs\FINALISED\00 Current version 00		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist		
Date First Issued:	October 2013	**Last Reviewed:**	November 2022
Amendment Dates:	November 2016, November 2022, June 2023	**Next Review Date:**	December 2025
Approved by:	Medication Safety Committee	**Date:**	December 2022
Endorsed by:	Drugs and Therapeutics Committee	**Date:**	December 2022
Standards Applicable:	NSQHS Standards:  NSMHS: N/A Child Safe Standards: N/A		

Printed or personally saved electronic copies of this document are considered uncontrolled

Healthy kids, healthy communities

Compassion | Excellence | Collaboration | Accountability | Equity | Respect

Neonatology | Community Health | Mental Health | Perth Children's Hospital