MONOGRAPH

Tobramycin (Inhaled) 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

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

DRUG CLASS

Aminoglycoside antibiotic.[1]

Tobramycin is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

Inhaled: Monitored (orange) antibiotic

- 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 tobramycin, other aminoglycosides or any component of the formulation.[2-4]

PRECAUTIONS

- In patients with a history of severe haemoptysis, there is a risk of further haemorrhage.[5]
- Tobi® capsules (tobramycin 28mg capsules for inhalation) are for inhalation only via the Podhaler® device and should NOT be administered via any other route.[4]
- Patients should be monitored for bronchospasm with the first dose of inhaled tobramycin.[3]
- In patients with previous long term use of an aminoglycoside (IV or inhaled use) or concomitant aminoglycoside use, there is an increased risk of ototoxicity.[5]

FORMULATIONS

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

- 80 mg/2mL Vial
- 500 mg/5mL Vial - kept in Pharmacy Compounding Service unit and to be used only for Hospital in the Home (HiTH) tobramycin IV doses.
- 300 mg/5mL inhalation solution.
- 28 mg capsules for inhalation.

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates and infants < 6 months of age: Inhaled tobramycin is not routinely used in neonates. Contact Infectious Disease or Clinical Microbiology Consultant for advice.

Inhalation (via nebuliser):

Bronchiectasis

Children ≥ 6 months and < 6 years old with *Bronchiectasis*:

- 80 mg twice daily (using the 80 mg/2mL vial) for 28 days, followed by 28 days of no inhaled tobramycin therapy before considering another course of inhaled tobramycin.[3]

Children ≥ 6 years old with *Bronchiectasis*:

- 300 mg twice daily for 28 days, followed by 28 days of no inhaled tobramycin therapy before considering another course of inhaled tobramycin.[1, 2, 4]

***Cystic Fibrosis*:**

Children ≥ 6 months to < 2 years old with *Cystic Fibrosis*:

- 150 mg twice daily for 28 days, followed by 28 days of no inhaled tobramycin therapy before considering another course of inhaled tobramycin.[3, 6]

Children ≥ 2 years old with *Cystic Fibrosis*:

- 300 mg twice daily for 28 days, followed by 28 days of no inhaled tobramycin therapy before considering another course of inhaled tobramycin.[1, 2, 7]

***Cystic Fibrosis*:**

Inhalation (via Podhaler® device):

- **Note**: Tobi® capsules (tobramycin 28mg capsules for inhalation) are for INHALATION route only via the Podhaler® device.

Children ≥ 6 years old:

- 112 mg (4 x 28 mg capsules) administered twice daily for 28 days, followed by 28 days of no inhaled tobramycin therapy before restarting.(1, 2, 4, 5)
- A new Podhaler® device should be used every seven (7) days.(4)

IV: Refer to the separate IV tobramycin ChAMP monograph

Renal impairment:

- As systemic absorption of tobramycin following nebulisation or inhalation is low, dose adjustment is not routinely required. However, caution should be taken if inhaled tobramycin is used in patients with renal impairment or failure. In these patients, tobramycin levels should be monitored and the tobramycin ceased if there is evidence of nephrotoxicity or an individual level greater than 2 mg/L.(2, 3)
- Renal function monitoring is recommended prior to initiation of inhaled tobramycin treatment and annually thereafter.(2) More frequent monitoring will be required for patients on other nephrotoxic medications.

Hepatic impairment:

- No dose adjustments are required for hepatic impairment(3)
- Refer to the IV tobramycin monograph for dosage adjustments required for systemic use.

ADMINISTRATION

Doses should be administered as close to 12 hourly as possible, if this is not possible, doses must be separated by a minimum of 6 hours.(4, 5)

Prior to Administration:

- The first dose of inhaled tobramycin must be given in hospital under the supervision of a health care professional. If the patient has previously tolerated inhaled tobramycin then this is not necessary.(3)
- Where possible it is recommended to measure lung function before and after the first dose of tobramycin and monitor for bronchospasm for 15 minutes post inhalation.(3, 5)
- Signs of bronchospasm include wheeze, cough, increased work of breathing or distress. In the event of bronchospasm in a child not using a bronchodilator, the test dose may be repeated using a bronchodilator.(3, 5)
- If there are other medications to be administered via the inhalation route, the other medications should be administered first, and the tobramycin administered last.(1, 4)

Preparation:

- The manufacturer recommends that Tobramycin 300 mg/5mL solution for inhalation only be used with a PARI Pro-neb® or a PARI LC PLUS® nebuliser.[2, 4] In practice, alternative nebulisers have been used.

Administering a dose via nebuliser:

Refer to Inhaled Medication Administration Guide.

- If using the IV solution of tobramycin for inhalation (80 mg/2mL) the required volume of the tobramycin solution should be diluted with sodium chloride 0.9% solution to produce a final volume of 4mL.
- The nebuliser bowl should be thoroughly cleaned between the administration of different nebulising solutions.

To administer a tobramycin 112 mg dose using Tobi® dry powder for inhalation:

- Refer to the product information for full instructions on administration.[4]
- A new Podhaler® device should be used every seven (7) days.[4]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Sodium chloride 0.9% may be used to dilute the 80 mg/2mL vial for nebulisation. The specific nebuliser solutions do not require dilution and should not be mixed with any other fluids or medications.[4]
- Refer to the IV tobramycin monograph for compatible fluids for intravenous administration.

MONITORING

- As systemic absorption of tobramycin following nebulisation or inhalation is low, dose adjustment is not routinely required. However, caution should be taken if inhaled tobramycin is used in patients with renal impairment or failure. In these patients, tobramycin levels should be monitored and the tobramycin ceased if there is evidence of nephrotoxicity or an individual level greater than 2mg/L.[2, 3]
- Renal function monitoring is recommended prior to initiation of inhaled tobramycin treatment and annually thereafter.[2] More frequent monitoring will be required for patients on other nephrotoxic medications.
- Patients lung function should be measured before and after the initial dose and patients should be monitored for bronchospasm.[5]

ADVERSE EFFECTS

Common: cough, bronchospasm, dysphonia, taste disturbances salivary hypersecretion, laryngitis, haemoptysis, throat pain, transient tinnitus (without hearing loss), malaise, sputum discolouration, nephrotoxicity and/or ototoxicity (in patients with renal impairment).[1, 5]

Rare: abdominal pain, asthenia, asthma, drowsiness, ear disorders, ear pain, epistaxis, hypoxia,

oral ulceration, lymphadenopathy, pain.[1, 5]

- For additional adverse effects seen with systemic therapy refer to the IV tobramycin monograph.

STORAGE

- 80 mg/2mL ampoule (DBL brand) should be protected from light and stored below 25˚C.[4]
- 500 mg/5mL vial (Tobra-Day®) should be protected from light and stored between 2 and 8˚C.[4]
- Tobramycin 300 mg/5mL solution for inhalation should be stored between 2 and 8˚C and protected from light.[4]
- If refrigeration is not possible, the tobramycin 300 mg/5mL solution for inhalation pouches (opened or sealed) may be stored at room temperature (up to a maximum of 25˚C) for up to 28 days.[4]
- Tobi® capsules for inhalation should be stored at room temperature (less than 30˚C) and protected from moisture and humidity. The capsules should be kept in the original packaging until ready to be administered. Each Podhaler® device should be discarded after 7 days.[4]

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 **inhaled tobramycin**. 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

Inhaled Medication Administration Guide

References

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