MONOGRAPH

Ethambutol 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

Antimycobacterial.[1]

INDICATIONS AND RESTRICTIONS

Ethambutol is indicated for use in the treatment of *Mycobacterium tuberculosis*, *Mycobacterium avium* complex and other non-tuberculosis mycobacterial infections.[1-3]

Ethambutol **must** be used in combination with other antimycobacterial agents.[1, 2]

Oral: Restricted (red) antimycobacterial

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to ethambutol or any component of the formulation.[2, 4]
- Ethambutol is contraindicated in patients with optic neuritis.[1, 2, 4-6]

PRECAUTIONS

- Ethambutol should be used cautiously in patients whose visual acuity and colour vision cannot be assessed (e.g. children less than 6 years old).[1-3, 5]

- Ophthalmologic studies (including visual acuity, visual fields and red/green colour vision) should be conducted in patients at baseline and then monthly for ALL patients on ethambutol therapy.[1, 2, 5, 6]
- Care should be taken in patients with pre-existing eye disease (e.g. cataracts, diabetic retinopathy) as further deterioration in vision may be difficult to evaluate.[1, 2]
- Ethambutol may precipitate a gout attack.[1]
- The dose of ethambutol requires adjustment in patients with a creatinine clearance less than 30 mL/minute/1.73m^2.[1, 2]

FORMULATIONS

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

- 100 mg and 400 mg tablets

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Ethambutol must always be used as part of a multidrug regimen and based on a patients lean body weight.[2, 4]

Neonates:

- Not routinely used in neonates less than 4 weeks of age, contact Infectious Disease or Clinical Microbiology consultants for advice.

Infants and Children (≥ 4 weeks to 18 years):

Tuberculosis (used for the first 2 months of a 6 month regimen)[7]:

- 20 mg/kg/day (to a maximum of 1600 mg) once daily. Dose range of 15-25 mg/kg/day may be used for ease of administration.[6-9]

The following dose bands may be used for ease of dosing[1, 7, 9-11]:

Weight	Dose	Number of tablets
≥ 1 kg to < 2 kg	20 mg	Crush a 100 mg tablet, mix with 10 mL of water and give 2 mL of the mixture immediately. Discard the remainder.
≥ 2 kg to < 3 kg	40 mg	Crush a 100 mg tablet, mix with 10 mL of water and give 4 mL of the mixture immediately. Discard the remainder.
≥ 3 kg to < 4 kg	70 mg	Crush a 100 mg tablet, mix with 10 mL of water and give 7 mL of the mixture immediately. Discard the remainder.
≥ 4 kg to < 8 kg	100 mg	1 x 100 mg
≥ 8 kg to < 12 kg	200 mg	2 x 100 mg
≥ 12 kg to < 16 kg	300 mg	3 x 100 mg
≥ 16 kg to < 25 kg	400 mg	1 x 400 mg

≥ 25 kg to < 30 kg	600 mg	1.5 x 400 mg
≥ 30 kg to < 35 kg	800 mg	2 x 400 mg
≥ 35 kg to < 65 kg	1200 mg	3 x 400 mg
≥ 65 kg	1600 mg	4 x 400 mg

Note: Crushed tablets do not disperse well in water. Mix thoroughly, measure the required dose and administer without delay.[12] Discard any remaining solution.

Other infections (e.g. non Tuberculosis *Mycobacterium avium* complex): 15-25 mg/kg/dose (to a maximum of 2.5 grams) once daily.[1, 2]

Dosing in Overweight and Obese Children: The optimal dose for obese or overweight patients has not been established. However, dosing based on lean body weight is recommended for patients within the normal weight range. Discuss dosing with infectious diseases team.[2, 6]

Renal impairment:

- eGFR calculator
- Use of ethambutol in patients with renal impairment increases the risk of optic neuritis.[1, 5]

eGFR (mL/minute/1.73m^2)	**Recommended dose**
≥ 30mL/minute/1.73m^2	No dose adjustment required
< 30mL/minute/1.73m^2	15 to 25 mg/kg/dose given three times per week

Hepatic impairment:

- Specific guidelines for dosage adjustments in hepatic impairment are not available; it appears no dosage adjustments are needed.[2]
- Ethambutol should be used cautiously in patients with hepatic disease as it is often used in conjunction with other hepatotoxic agents.[2, 6]

ADMINISTRATION

Oral:

- Tablets may be administered with or without food. If stomach upset occurs, taking the tablets with food may assist.[2, 4, 6, 12]
- If unable to swallow the tablet whole, it may be crushed and mixed with apple juice, apple sauce or chocolate pudding to mask the bitter taste.[2, 6, 12]

MONITORING

- Ophthalmologic studies (including visual acuity, visual fields and red/green colour vision) should be conducted in patients at baseline and then monthly for ALL patients on ethambutol therapy.[1, 2, 5, 6]

- In young children who are not able to report changes in vision, patients should be monitored for increased eye rubbing or blinking or decreased ability to grasp small objects.[2]
- Renal, hepatic and haematologic tests should also be conducted at baseline and periodically whilst undergoing treatment with ethambutol.[1, 2, 6]

ADVERSE EFFECTS

Common: Optic neuritis, hyperuricaemia, nerve disorders.[1, 5]

Optic neuritis requires discontinuation and is dose related, usually reversible and characterised by a reduction in visual acuity, scotoma or colour blindness. It is more likely to occur with daily doses >15 mg/kg and less likely to occur in patients with normal renal function and course duration less than 2 months.[1, 5]

Infrequent: Headache, confusion, disorientation, hallucinations, malaise, nausea, vomiting, anorexia, abdominal pain[1]

Rare:, Jaundice, acute gout, neutropenia, eosinophilia, thrombocytopenia, renal failure, allergic reaction (rash, fever, joint pain, Stevens-Johnson syndrome), peripheral neuritis, tubulointerstitial nephritis.[1, 5]

STORAGE

- Store tablets at <25˚C.[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 **ethambutol**. 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

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