#### **MONOGRAPH**

## **LABETALOL**

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	Intravenous (Critical Care Areas), Oral (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					
<u>Dosage/Dosage</u> <u>Adjustments</u>	Administration	<u>Compatibility</u>	Monitoring		

#### **DRUG CLASS**

Labetalol is a nonselective beta-blocker, which blocks beta-1, beta-2 and alpha-1 receptors<sup>1</sup>

#### INDICATIONS AND RESTRICTIONS<sup>1</sup>

- Hypertension
- Hypertensive emergency (intravenous)

## CONTRAINDICATIONS1

- Hypersensitivity to labetalol or any component of the formulation
- Cardiogenic and hypovolaemic shock
- Severe bradycardia
- Second or third degree AV block
- Sick sinus syndrome (without pacemaker)
- Severe hypotension
- Uncontrolled heart failure
- Severe or poorly controlled asthma

#### **PRECAUTIONS**

- First degree AV block may worsen¹
- Hyperthyroidism may mask clinical signs. Abrupt withdrawal may exacerbate symptoms of hyperthyroidism<sup>1</sup>
- Hepatic impairment use with caution, increases bioavailability<sup>2</sup>
- Phaeochromocytoma may aggravate hypertension¹
- Patients with a history of anaphylactic reactions may reduce response to usual doses of adrenaline (epinephrine) for anaphylaxis<sup>1</sup>
- Diabetes may mask signs of hypoglycaemia<sup>1</sup>
- Myasthenic symptoms may worsen<sup>1</sup>
- Severe peripheral arterial disease, Raynaud's phenomenon may impair circulation and exacerbate symptoms<sup>1</sup>

#### **FORMULATIONS**

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

- 50 mg/10 mL ampoule
- 100 mg, 200 mg tablets

Imprest location: Formulary One

#### **DOSAGE & DOSAGE ADJUSTMENTS**

**Neonates: Refer to Neonatal Medication Protocols** 

#### **Renal impairment:**

- eGFR calculator
- No dosage adjustment required<sup>2</sup>

#### **Hepatic impairment:**

 Dosage reduction may be necessary due to decreased metabolism and increased oral bioavailability<sup>2</sup>

#### Hypertensive emergency (Continuous IV Infusion):

- Child (≥4 weeks –18 years): 0.25 3 mg/kg/hour (maximum initial rate 120 mg/hour).<sup>2, 3</sup>
  - Start at lower end of dosage range and titrate at intervals of at least 15 minutes to blood pressure response<sup>2, 4</sup>
  - An IV bolus may be administered if needed prior to starting continuous infusion<sup>3</sup>

#### **Hypertension (IV Intermittent Bolus):**

• Child (≥4 weeks –18 years): 0.2 – 1 mg/kg/dose. Maximum 40 mg per dose. Dose may be repeated every 10 minutes until target blood pressure reached<sup>2, 3</sup>

## Chronic Hypertension (Oral):

Child (≥4 weeks –18 years): 1 – 3 mg/kg/day, usually in 2 divided doses. Maximum 10–12 mg/kg/day (up to 1200 mg/day)<sup>2, 5</sup>

#### **ADMINISTRATION**

## Intravenous infusion (standard concentration):

- Peripheral Intravenous Catheter (PIVC): 30 mg in 30 mL (1 mg/mL).
   Diluted solution is only stable for 6 hours.<sup>4, 6</sup>
- Central Venous Access Device (CVAD): 250 mg in 50 mL (5 mg/mL undiluted)<sup>6</sup>

## Intravenous injection:

Administer undiluted (5 mg/mL) slowly over 2 minutes<sup>2, 6</sup>; maximum 10 mg/minute<sup>2</sup>

#### Oral:

 Labetalol can be taken with or without food but should be taken in a consistent manner with regards to food<sup>2</sup>

## **COMPATIBILITY (LIST IS NOT EXHAUSTIVE)**

**Compatible fluids:** Glucose 5%, glucose in sodium chloride solutions, Hartmann's, Plasma-Lyte 148 (at Y-site), Ringer's, sodium chloride 0.9%.<sup>6</sup>

**Compatible at Y-site:** Amikacin, aminophylline, amiodarone, atracurium, calcium chloride, calcium gluconate, ceftazidime, clonidine, dexmedetomidine, digoxin, dobutamine, dopamine, esmolol, fentanyl, fluconazole, gentamicin, glyceryl trinitrate, hydromorphone, insulin (Novorapid), lidocaine, magnesium sulfate, metaraminol, metoclopramide, metronidazole, midazolam, milrinone, morphine sulfate, noradrenaline (norepinephrine), ondansetron, phenobarbital, potassium chloride, propofol, sodium acetate, sodium nitroprusside, tobramycin, trimethoprimsulfamethoxazole, suxamethonium, vancomycin, vecuronium, verapamil.<sup>3, 6</sup>

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

**INCOMPATIBLE drugs:** Albumin, aciclovir, amphotericin B liposomal (AmBisome), benzylpenicillin, cefepime, cefotaxime, ceftriaxone, dexamethasone, diazepam, furosemide, heparin sodium, hydrocortisone sodium succinate, insulin (Actrapid), micafungin, phenytoin, piperacillin-tazobactam.<sup>3, 6</sup>

#### **MONITORING**

#### **Intravenous Administration:**

- Continuous cardiac monitoring required during IV infusion.<sup>6</sup>
- Monitor blood pressure and heart rate 5 to 10 minutes after giving IV injection or increasing rate of IV infusion.<sup>6</sup>

- Monitor for rapid reduction of blood pressure Aim for a reduction of one third of the final blood pressure target in the first 24 hours of therapy.
- Assess liver function at first sign of liver dysfunction.<sup>5</sup>
- Patient to remain lying down during and for up to 3 hours after IV administration to prevent orthostatic hypotension.<sup>6</sup>
- Duration of action of IV labetalol is 6 hours or more, monitor patient for at least 6 hours after stopping IV infusion.<sup>6</sup>

#### **Oral Administration:**

- Monitor for a reduction in standing blood pressure within 1 to 3 hours of initial dose.<sup>5</sup>
- Monitor liver function regularly or at first sign of liver dysfunction.<sup>5</sup>

## **ADVERSE EFFECTS<sup>1</sup>**

**Common:** Bradycardia, hypotension, orthostatic hypotension, initial transient worsening of heart failure, nausea, diarrhoea, bronchospasm, dyspnoea, cold extremities, exacerbation of Raynaud's phenomenon, fatigue, dizziness, abnormal vision, alteration of glucose and lipid metabolism.

**Infrequent or rare:** Hallucinations, insomnia, nightmares, heart block, rash, alopecia, exacerbation of psoriasis, impotence, muscle cramp, nasal congestion, hypersensitivity reaction, thrombocytopenia, increased aminotransferase concentrations, hepatotoxicity.

## STORAGE<sup>7</sup>

- Ampoules for injection Store below 25 °C.
- Diluted solutions for IV infusion are stable for 6 hours when stored below 25 °C or 24 hours when stored at 2 to 8 °C.<sup>6</sup>
- Tablets Store below 30 °C.

#### **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.

#### References

- 1. Handbook AM. Australian Medicines Handbook Adelaide, South Australia: AUSTRALIAN MEDICINES HANDBOOK; 2023. Available from: <a href="https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/">https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/</a>.
- 2. UpToDate Waltham, MA: Lexicomp; 2023. Available from: <a href="https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/search">https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/search</a>.
- 3. Clinical Pharmacology Tampa. FL: Gold Standard, Inc.; 2023. Available from: <a href="http://www.clinicalpharmacology.com.pklibresources.health.wa.gov.au">http://www.clinicalpharmacology.com.pklibresources.health.wa.gov.au</a>.
- 4. Committee PF. BNF for children 2023. Available from: <a href="https://www-medicinescomplete-com.pklibresources.health.wa.gov.au/mc/bnfc/current/">https://www-medicinescomplete-com.pklibresources.health.wa.gov.au/mc/bnfc/current/</a>.

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

- Micromedex (electronic version) Greenwood Village, Colorado, USA: Truven Health Analytics; 2023. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/
- Society of Hospital Pharmacists of Australia. Australian Injectable Drugs Handbook: Health Communication Network: 2023. Available from: https://aidh-hcn-comau.pklibresources.health.wa.gov.au/browse/about aidh.
- MIMS Australia. MIMS Online St Leonards, N.S.W: MIMS Australia Pty Ltd; 2023. Available from: https://www-mimsonline-com-au.pklibresources.health.wa.gov.au/Search/Search.aspx.

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# Healthy kids, healthy communities

Compassion

Excellence Collaboration Accountability

Respect

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