

# PHENOBARBITAL (PHENOBARBITONE)

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| <b>Indication</b> | <ul style="list-style-type: none"> <li>• Control of acute seizures (generalised and partial) and status epilepticus<sup>1</sup></li> <li>• Sedation during NAS<sup>2</sup></li> <li>• Preparation for HIDA scan<sup>3</sup> <ul style="list-style-type: none"> <li>○ Dosing as per local nuclear medicine protocol</li> </ul> </li> </ul> |
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| <b>ORAL</b> | <b>Presentation</b>                          | <ul style="list-style-type: none"> <li>• Oral solution: 3 mg in 1 mL <ul style="list-style-type: none"> <li>○ Commercial oral solution contains 9.6% alcohol</li> </ul> </li> </ul>   |  |
|             | <b>Dosage<sup>1</sup></b><br><b>seizures</b> | <ul style="list-style-type: none"> <li>• Maintenance dose: 2–5 mg/kg/day <ul style="list-style-type: none"> <li>○ Commence 12–24 hours after IV or IM loading dose<sup>1</sup></li> <li>○ May be divided into 12 hourly doses (at SMO discretion)<sup>3-5</sup></li> </ul> </li> </ul>  |   |
|             | <b>Dosage<sup>6</sup></b><br><b>NAS</b>      | <ul style="list-style-type: none"> <li>• Loading dose: 10–15 mg/kg</li> <li>• Maintenance dose: 2.5 mg/kg every 12 hours (5 mg/kg/day) <ul style="list-style-type: none"> <li>○ Commence 12 hours after loading dose</li> </ul> </li> </ul>   |   |
|             | <b>Preparation</b>                           | <ul style="list-style-type: none"> <li>• Draw up prescribed dose into oral/enteral syringe</li> </ul>   |   |
|             | <b>Administration</b>                        | <ul style="list-style-type: none"> <li>• Oral/OGT/NGT before feeds (to reduce the risk of vomiting) <ul style="list-style-type: none"> <li>○ Limited evidence to inform recommendation: <ul style="list-style-type: none"> <li>○ <i>If large vomit within 15 minutes of receiving dose, repeat full dose</i></li> <li>○ <i>If large vomit after 15 minutes or more of receiving dose, do not repeat dose</i></li> </ul> </li> </ul> </li> </ul> |   |

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| <b>INTRAVENOUS</b>    | <b>Seizures</b>  |   |  |
|                       | <b>Presentation</b>  | <ul style="list-style-type: none"> <li>• Ampoule: 200 mg in 1 mL (as phenobarbital sodium)</li> </ul>   |  |
|                       | <b>Seizures loading dose (via IV infusion)</b>   |   |  |
|                       | <b>Dosage</b>  | <ul style="list-style-type: none"> <li>• If birthweight <b>1500 g or more<sup>1</sup></b>: 20 mg/kg <ul style="list-style-type: none"> <li>○ If required, may give additional doses of 10 mg/kg every 20–30 minutes</li> <li>○ Maximum dose 40 mg/kg<sup>3,5</sup></li> </ul> </li> <li>• If birthweight <b>less than 1500 g<sup>4</sup></b>: 10 mg/kg <ul style="list-style-type: none"> <li>○ If required, may give an additional dose of 10 mg/kg</li> </ul> </li> </ul> |  |
|                       | <b>Preparation</b>   | <ul style="list-style-type: none"> <li>• Draw up 200 mg (1 mL) and make up to 10 mL total volume with water for injection<sup>7</sup> <ul style="list-style-type: none"> <li>○ <i>Concentration now equal to 20 mg/mL</i></li> </ul> </li> <li>• Draw up prescribed dose (from the 20 mg/mL solution) plus sufficient volume to prime infusion line</li> <li>• Prime infusion line and reduce total syringe volume to prescribed dose</li> </ul>                            |  |
|                       | <b>Administration</b>  | <ul style="list-style-type: none"> <li>• Infuse via syringe driver over 20–30 minutes <ul style="list-style-type: none"> <li>○ No faster than 1 mg/kg/minute<sup>7</sup></li> </ul> </li> <li>• On completion, disconnect syringe and infusion line</li> <li>• Flush access port at same rate as infusion</li> </ul>  |  |
|                       | <b>Seizures maintenance dose (via IV injection)</b>  |   |  |
|                       | <b>Dosage</b>  | <ul style="list-style-type: none"> <li>• Maintenance dose: 2–5 mg/kg/day <ul style="list-style-type: none"> <li>○ Commence 12–24 hours after loading dose<sup>1</sup></li> <li>○ May be divided into 12 hourly doses (at SMO discretion)<sup>3-5</sup></li> </ul> </li> </ul>   |  |
| <b>Preparation</b>    | <ul style="list-style-type: none"> <li>• Draw up 200 mg (1 mL) and make up to 10 mL total volume with water for injection<sup>7</sup> <ul style="list-style-type: none"> <li>○ <i>Concentration now equal to 20 mg/mL</i></li> </ul> </li> <li>• Draw up prescribed dose (from the 20 mg/mL solution)</li> </ul> |   |  |
| <b>Administration</b> | <ul style="list-style-type: none"> <li>• IV injection over 5 minutes <ul style="list-style-type: none"> <li>○ No faster than 1 mg/kg/minute<sup>7</sup></li> </ul> </li> </ul>   |   |  |

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| <b>INTRAVENOUS</b>    | <b>NAS</b>  |   |  |
|                       | <b>Presentation</b>   | <ul style="list-style-type: none"> <li>• Ampoule: 200 mg in 1 mL (as phenobarbital sodium)</li> </ul>   |   |
|                       | <b>NAS loading dose (via IV infusion)</b>   |   |   |
|                       | <b>Dosage</b>   | <ul style="list-style-type: none"> <li>• Loading dose: 10–15 mg/kg</li> </ul>   |   |
|                       | <b>Preparation</b>  | <ul style="list-style-type: none"> <li>• Draw up 200 mg (1 mL) and make up to 10 mL total volume with water for injection<sup>7</sup> <ul style="list-style-type: none"> <li>◦ Concentration now equal to 20 mg/mL</li> </ul> </li> <li>• Draw up prescribed dose (from the 20 mg/mL solution) plus sufficient volume to prime infusion line</li> <li>• Prime infusion line and reduce total syringe volume to prescribed dose</li> </ul> |   |
|                       | <b>Administration</b>   | <ul style="list-style-type: none"> <li>• Infuse via syringe driver over 20–30 minutes                             <ul style="list-style-type: none"> <li>◦ No faster than 1 mg/kg/minute<sup>7</sup></li> </ul> </li> <li>• On completion, disconnect syringe and infusion line</li> <li>• Flush access port at same rate as infusion</li> </ul>  |   |
|                       | <b>NAS maintenance dose (via IV injection)</b>  |   |   |
|                       | <b>Dosage</b>   | <ul style="list-style-type: none"> <li>• Maintenance dose: 2.5 mg/kg every 12 hours (5 mg/kg/day)                             <ul style="list-style-type: none"> <li>◦ Commence 12 hours after loading dose</li> </ul> </li> </ul>  |   |
| <b>Preparation</b>    | <ul style="list-style-type: none"> <li>• Draw up 200 mg (1 mL) and make up to 10 mL total volume with water for injection<sup>7</sup> <ul style="list-style-type: none"> <li>◦ Concentration now equal to 20 mg/mL</li> </ul> </li> <li>• Draw up prescribed dose (from the 20 mg/mL solution)</li> </ul> |   |   |
| <b>Administration</b> | <ul style="list-style-type: none"> <li>• IV injection over 5 minutes                             <ul style="list-style-type: none"> <li>◦ No faster than 1 mg/kg/minute<sup>7</sup></li> </ul> </li> </ul>  |   |   |

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| <b>IM</b> | <b>Presentation</b>    | <ul style="list-style-type: none"> <li>• Ampoule: 200 mg in 1 mL (as phenobarbital sodium)</li> </ul>  |  |
|           | <b>Dosage seizures</b> | <ul style="list-style-type: none"> <li>• Loading dose: 20 mg/kg                             <ul style="list-style-type: none"> <li>◦ If required, may give additional doses of 10 mg/kg every 20–30 minutes</li> <li>◦ Maximum dose 40 mg/kg<sup>3,5</sup></li> </ul> </li> <li>• Maintenance dose: 2–5 mg/kg/day                             <ul style="list-style-type: none"> <li>◦ Commence 12–24 hours after loading dose<sup>1</sup></li> <li>◦ May be divided into 12 hourly doses (at SMO discretion)<sup>3-5</sup></li> </ul> </li> </ul> |   |
|           | <b>Preparation</b>     | <ul style="list-style-type: none"> <li>• Draw up prescribed dose</li> </ul>  |   |
|           | <b>Administration</b>  | <ul style="list-style-type: none"> <li>• IM injection into thickest part of the vastus lateralis (antero-lateral thigh)                             <ul style="list-style-type: none"> <li>◦ Maximum 0.5 mL per site<sup>8</sup></li> </ul> </li> </ul>  |   |

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| <b>Special considerations</b> | <ul style="list-style-type: none"> <li>• Cautions                             <ul style="list-style-type: none"> <li>◦ If renal or hepatic impairment<sup>1,2</sup></li> <li>◦ If IV administration rate exceeded<sup>2</sup>, risk of severe respiratory depression which may require ventilation<sup>9</sup></li> <li>◦ Do not cease abruptly (especially after prolonged use), reduce dosage gradually over days or weeks<sup>10</sup></li> </ul> </li> <li>• For NAS, refer to Queensland Clinical Guidelines: <i>Perinatal substance use: neonata</i><sup>6</sup> for                             <ul style="list-style-type: none"> <li>◦ Titration recommendations according to assessment</li> <li>◦ Weaning criteria and reduction schedule</li> <li>◦ Oral route preferred for NAS</li> </ul> </li> <li>• For hepatobiliary scintigraphy: evidence of efficacy uncertain<sup>11-13</sup></li> <li>• If prescribed for palliative care                             <ul style="list-style-type: none"> <li>◦ May be administered subcutaneously in consultation with Paediatric Palliative Care Service and pharmacist</li> </ul> </li> <li>• UAC route                             <ul style="list-style-type: none"> <li>◦ Consult with neonatologist/paediatrician prior to use and refer to Queensland Clinical Guideline: <i>Neonatal medicines</i><sup>14</sup></li> </ul> </li> </ul> |
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| <b>Therapeutic monitoring</b> | <ul style="list-style-type: none"> <li>• Treatment for NAS does not require levels unless indicated by clinical condition</li> <li>• Trough level <ul style="list-style-type: none"> <li>○ Prior to 5<sup>th</sup> maintenance dose (or earlier at SMO discretion)</li> <li>○ Therapeutic range<sup>2</sup>: 15–40 mg/L</li> </ul> </li> </ul>   |
| <b>Monitoring</b>             | <ul style="list-style-type: none"> <li>• For seizure management <ul style="list-style-type: none"> <li>○ Cardiorespiratory</li> <li>○ FBC if prolonged therapy<sup>2</sup></li> <li>○ Resources to mechanically ventilate, if required</li> </ul> </li> <li>• For NAS <ul style="list-style-type: none"> <li>○ Assessment of clinical condition</li> <li>○ Cardiorespiratory (if dose 10 mg/kg/day or more), or if nursed prone</li> </ul> </li> <li>• Extravasation risk, may cause necrosis<sup>9</sup></li> </ul>   |
| <b>Compatibility</b>          | <ul style="list-style-type: none"> <li>• Fluids <ul style="list-style-type: none"> <li>○ 5% glucose<sup>7</sup>, 0.9% sodium chloride<sup>7</sup></li> </ul> </li> <li>• Y-site <ul style="list-style-type: none"> <li>○ Consult pharmacy for advice<sup>7</sup></li> </ul> </li> </ul>  |
| <b>Incompatibility</b>        | <ul style="list-style-type: none"> <li>• PN and fat emulsion <ul style="list-style-type: none"> <li>○ Co-infusion with phenobarbital not recommended (evidence limited)</li> <li>○ If unavoidable, seek pharmacist advice first, filter infusion and flush before and after</li> </ul> </li> <li>• Fluids <ul style="list-style-type: none"> <li>○ No information<sup>7</sup></li> </ul> </li> <li>• Drugs <ul style="list-style-type: none"> <li>○ Adrenaline (epinephrine)<sup>7</sup>, amiodarone<sup>7</sup>, atracurium<sup>7</sup>, benzylpenicillin<sup>7</sup>, caspofungin<sup>7</sup>, cefotaxime<sup>7</sup>, cefoxitin<sup>7</sup>, clindamycin<sup>7</sup>, dobutamine<sup>7</sup>, erythromycin<sup>7</sup>, esmolol<sup>7</sup>, haloperidol lactate<sup>7</sup>, ketamine<sup>7</sup>, lidocaine<sup>7</sup>, midazolam<sup>7</sup>, mycophenolate mofetil<sup>7</sup>, noradrenaline (norepinephrine)<sup>7</sup>, protamine<sup>7</sup>, pyridoxine<sup>7</sup>, ranitidine<sup>7</sup>, suxamethonium<sup>7</sup>, thiamine<sup>7</sup>, verapamil<sup>7</sup></li> </ul> </li> </ul> |
| <b>Interactions</b>           | <ul style="list-style-type: none"> <li>• Caution if co-administered with other CNS depressants (e.g. benzodiazepines, narcotics, antihistamines or anaesthetics<sup>10</sup>)</li> </ul>   |
| <b>Stability</b>              | <ul style="list-style-type: none"> <li>• Ampoule <ul style="list-style-type: none"> <li>○ Store below 25 °C.<sup>10</sup> Protect from light<sup>7</sup></li> </ul> </li> <li>• Oral solution <ul style="list-style-type: none"> <li>○ Discard 4 weeks after opening or as per local infection control policy (limited evidence)</li> </ul> </li> </ul>  |
| <b>Side effects</b>           | <ul style="list-style-type: none"> <li>• Blood: hypocalcaemia, folate deficiency<sup>2</sup></li> <li>• Circulatory: hypotension<sup>9</sup>, profound shock with peripheral vascular collapse<sup>2</sup></li> <li>• Immune: allergic skin rashes (including SJS)<sup>9</sup></li> <li>• Nervous: sedation<sup>9</sup>, irritability<sup>9</sup>, hyperexcitability<sup>9</sup>, prolonged coma<sup>2</sup>, depressed or absent reflexes<sup>2</sup></li> <li>• Respiratory: respiratory depression<sup>9</sup></li> </ul>   |
| <b>Actions</b>                | <ul style="list-style-type: none"> <li>• Long acting barbiturate with sedative, hypnotic and anticonvulsant properties<sup>10</sup> <ul style="list-style-type: none"> <li>○ Half-life of several days</li> </ul> </li> </ul>  |
| <b>Abbreviations</b>          | CNS: central nervous system, HIDA: hepatobiliary iminodiacetic acid, IM: intramuscular, IV: intravenous, OGT: orogastric tube, NAS: neonatal abstinence syndrome, NGT: nasogastric tube, PN: parenteral nutrition, SJS: Stevens Johnson Syndrome, SMO: most senior medical officer   |
| <b>Keywords</b>               | Barbiturate, antiepileptic, phenobarbitone, phenobarbital, sedative, hypnotic, epilepsy, seizure, anticonvulsant, NAS, neonatal abstinence syndrome  |

The Queensland Clinical Guideline *Neonatal Medicines* is integral to and should be read in conjunction with this monograph. Refer to the disclaimer. Destroy all printed copies of this monograph after use.

## References

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## Document history

| ID number          | Effective  | Review     | Summary of updates  |
|--------------------|------------|------------|---|
| NMedQ21.062-V1-R26 | 16/08/2021 | 16/08/2026 | Endorsed by Queensland Neonatal Services Advisory Group   |
| NMedQ21.062-V2-R26 | 25/03/2024 | 16/08/2026 | <ul style="list-style-type: none"> <li>• IV dosages separated by indication into different tables (NAS and seizure)</li> <li>• Added duration of IV infusion administration (over 20–30 minutes)</li> <li>• Added duration of IV injection administration (over 5 minutes)</li> </ul> |

## QR code

