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NOTICE: PHENOBARBITAL/PHENOBARBITONE 30 MG TABLETS - STOCK SUPPLY SHORTAGE AND THE PROPOSED THERAPEUTIC ALTERNATIVES.

Phenobarbital 30 mg tablets are currently in short supply as the only registered supplier in the country has not yet passed a SAHPRA good manufacturing inspection. The National Department of Health has sourced stock through a Section 21 authorisation, which has been approved. This stock, however, will only be available from 19 August 2026.

As previously communicated, phenobarbital 16mg/5ml 100ml syrup has been withdrawn from the market (Circular Reference: AMD17022025/01, 20 February 2025). Given the current stock shortage of phenobarbital tablets, using crushed tablets mixed with liquid or food for administration as an alternative to the syrup is no longer an option.

The use of the approved Section 21 supply of phenobarbital injection remains stable and product can be used either intramuscularly (IM) or by slow intravenous (IV) injection [https://www.health.gov.za/wp-content/uploads/2025/11/Section-21-Authorisation-re-Phenobarbitone-200mg-INJ-1mL-08-May-2026.pdf].

The Primary Healthcare and Paediatric Hospital Level Standard Treatment Guidelines (STGs) recommend the use of phenobarbital oral therapy for several indications. In 2025, the Epilepsy Subcommittee of the National Essential Medicines List Committee updated the epilepsy STGs and related treatment algorithms reducing the indications for phenobarbital. Please refer to the latest published STGs for the updated antiseizure medicine indications and prescribing guidance.

For most indications levetiracetam can be used as an alternative during the phenobarbital stock shortage. Please consult the table below for full prescribing recommendations.

Alternative Treatments by Indication and Level of Care During Phenobarbital 30mg Tablet Stock Shortage

Level of Care	Chapter	Indication	Current Standard Treatment Guideline Recommendation	Alternative During Phenobarbital 30mg Tablet Stock Shortage
Primary Health Care Level	Chapter 15 Central Nervous System Conditions	Medicine management and supportive care of status epilepticus in children < 13 years (established status 10-30 minutes after seizure)	**LEVEL 2 INTERVENTION:** If no vascular access: • Phenobarbital, IM 20mg/kg (Doctor prescribed) o Slow IM Injection. **OR** if no IM formulation available: • Levetiracetam oral, crushed and given by nasogastric tube, 60 mg/kg as a single dose (maximum dose: 4500 mg). **OR** • Phenobarbital, oral, crushed and given by nasogastric tube, 20 mg/kg as a single dose. **Note:** if no response to phenobarbital IM or oral after 5-20 minutes, levetiracetam oral may be given via NG tube, but avoid repeating oral phenobarbital as it may take over an hour to achieve therapeutic concentrations and repeat doses increases the risk of respiratory depression.	**LEVEL 2 INTERVENTION:** If no vascular access: • Phenobarbital, IM 20mg/kg (Doctor prescribed) o Slow IM Injection. **OR** If no IM formulation available: • Levetiracetam oral, crushed and given by nasogastric tube, 60 mg/kg as a single dose (maximum dose: 4500 mg).
Primary Health Care Level	Chapter 15 Central Nervous System Conditions	Epilepsy In Children <13 Years of Age	**Phenobarbital** may be initiated in infants under 6 months of age or for children with severe or profound intellectual disability, for whom the adverse effects will not interfere with their care or activities of daily living. In children who are controlled on phenobarbital, cross-titration onto another suitable ASM should be undertaken by 2 years of age.	Refer to next level of care for assessment and cross-titration to a suitable ASM.
Primary Health Care Level	Chapter 21 Emergencies And Injuries	Seizures And Status Epilepticus	If no response after two consecutive doses of either midazolam or diazepam, and if the convulsion has lasted more than 20 minutes: **ADD** • Phenobarbital, oral, crushed and given by nasogastric tube, 20 mg/kg as a single dose. See dosing table: Chapter 23.	If no vascular access: • Phenobarbital, IM 20mg/kg (Doctor prescribed) o Slow IM Injection. **OR** If no IM formulation available: • Levetiracetam oral, crushed and given by nasogastric tube, 60 mg/kg as a single dose (maximum dose: 4500 mg).
Paediatric Hospital Level	Chapter 2 Alimentary Tract	Diarrhoea, Acute	Severe hypernatraemic dehydration (sodium > 170 mmol/L (discuss with specialist paediatrician): If convulsions are considered likely, (decreased level of consciousness, hyper-irritable child), in the setting of high serum sodium, consider the use of prophylactic anticonvulsants: • Phenobarbital, IV, 20 mg/kg as a single dose. **OR** If IV phenobarbitone not available: • Phenobarbital, oral, 20–30 mg/kg as a single dose.	If IV Phenobarbital not available: • Levetiracetam, oral, 60mg/kg/dose as a single dose (Maximum dose 4500mg).
Paediatric Hospital Level	Chapter 13 The Nervous System	Medicine management and supportive care of status epilepticus in children < 13 years	**LEVEL 2 INTERVENTION:** If vascular access is not available: • Phenobarbital, IM 20 mg/kg. o Slow IM injection	**LEVEL 2 INTERVENTION:** If vascular access is not available: • Phenobarbital, IM 20 mg/kg. o Slow IM injection

Level of Care	Chapter	Indication	Current Standard Treatment Guideline Recommendation	Alternative During Phenobarbital 30mg Tablet Stock Shortage
		(established status 10-30 minutes after seizure)	**OR** <u>if no IM formulation available:</u> • Levetiracetam oral, crushed and given by nasogastric tube 60 mg/kg as a single dose (Maximum dose: 4500 mg). **OR** • Phenobarbital, oral, crushed and given by nasogastric tube, 20 mg/kg as a single dose. **Note:** Avoid repeating oral phenobarbital as it may take over an hour to achieve therapeutic concentrations, and repeat doses increase the risk of respiratory depression. If no response to phenobarbital IM or oral after 5-20 minutes, levetiracetam oral may be given via nasogastric tube.	**OR** <u>If no IM formulation available:</u> • Levetiracetam oral, crushed and given by nasogastric tube, 60 mg/kg as a single dose (Maximum dose: 4500 mg).
Paediatric Hospital Level	Chapter 13 The Nervous System	Epilepsy In Children <13 Years of Age	**Phenobarbital** may be initiated in infants under 6 months of age or children with severe or profound intellectual disability, for whom the adverse effects will not interfere with their care or activities of daily living. In children who are established on phenobarbital, cross-titration onto another suitable ASM should be undertaken by 2 years of age.	Because of the long-titration period for lamotrigine, cross-titration from phenobarbital to either valproate or levetiracetam is recommended, with later cross-titration to lamotrigine if indicated. • Valproate oral. o 20 mg/kg/day divided 12 hourly. o Usual range: 20–30 mg/kg/day. **OR** • Levetiracetam, oral, 40-60mg/kg/dose (Maximum dose 4500mg). Levetiracetam, oral, • Infants 1 to < 6 months: o Initial dose: 7 mg/kg/dose twice daily. o Increase dosage every 2 weeks by 7 mg/kg/dose twice daily based on response and tolerability to the recommended dose of 21 mg/kg/dose twice daily. • Infants ≥ 6 months and children < 4 years: o Initial dose: 10 mg/kg/dose twice daily. o Increase dosage every 2 weeks by 10 mg/kg/dose twice daily based on response and tolerability to the recommended dose of 25 mg/kg/dose twice daily. • Children ≥ 4 years to 12 years: o Initial: 10 mg/kg/dose twice daily. o Increase dosage every 2 weeks by 10 mg/kg/dose twice daily based on response and tolerability to the recommended dose of 30 mg/kg/dose twice daily. If valproate is used in girls 10 years and older, it should be doctor prescribed with an "Acknowledgment of risk form" and effective family planning as necessary

Level of Care	Chapter	Indication	Current Standard Treatment Guideline Recommendation	Alternative During Phenobarbital 30mg Tablet Stock Shortage
Paediatric Hospital Level	Chapter 14 Child and Adolescent Psychiatry	Opioid Withdrawal	For CNS disturbances (e.g. seizures): • Phenobarbitone, oral. ○ 5 mg/kg/dose 12 hourly or daily. **OR** • Phenytoin, oral. ○ 5 mg/kg/day in 2–3 divided doses. ○ Maximum dose: 300 mg daily. ○ Maintenance dose: 5–8 mg/kg/day.	Seizures are not a usual manifestation of opioid withdrawal. If epileptic seizures do occur, manage as for an acute seizure (See Paediatric Hospital Level Chapter 13 The Nervous System Standard Treatment Guidelines 13.1: Epileptic seizures, 13.2: Status epilepticus and 13.2.1: Epileptic seizures and status epilepticus in children < 13).
Paediatric Hospital Level	Chapter 18 Poisoning	Isoniazid Poisoning	Benzodiazepines and phenobarbital may be used to control seizures (whilst pyridoxine is being prepared/given). Phenytoin should be avoided (due to potential cardiotoxicity).	Phenobarbital, IV 20mg/kg over 20 minutes <u>If no vascular access:</u> • Phenobarbital, IM 20mg/kg (Doctor prescribed) ○ Slow IM Injection. **OR** <u>If no IM formulation available:</u> • Levetiracetam oral, crushed and given by nasogastric tube, 60 mg/kg as a single dose (maximum dose: 4500 mg). Benzodiazepines may be used to control seizures (whilst pyridoxine is being prepared/given). If seizures persist then midazolam infusion/ propofol in ICU.
Paediatric Hospital Level	Chapter 19 Prematurity and Neonatal Conditions	Hypoxia-Ischaemia of the Newborn (Perinatal Hypoxia/Hypoxic-Ischaemic Encephalopathy (HIE))	Seizure Control Administer anticonvulsants with monitoring of cardiorespiratory function. • Phenobarbitone, IV: ○ Loading dose: 20 mg/kg over 10 minutes. ○ Refractory seizures: Additional 10 mg/kg up to 40 mg/kg. Maintenance: • Phenobarbitone, IV or oral: ○ 4 mg/kg/day beginning 12–24 hours after the loading dose.	• Levetiracetam, oral, 40-60mg/kg/dose (Maximum dose 4500mg). ○ Loading dose: 40 mg/kg IV. ○ Second loading dose: 20 mg/kg IV if required. ○ Maintenance: 40–60 mg/kg/day IV or orally 12 hourly.
Paediatric Hospital Level	Chapter 19 Prematurity and Neonatal Conditions	Seizures, Neonatal	**Seizure Control** Administer anticonvulsants with monitoring of cardiorespiratory function. • Phenobarbitone, IV. ○ Loading dose: 20 mg/kg administered over 10 minutes. ○ Refractory seizures: Additional 10 mg/kg/dose up to 40 mg/kg. Maintenance: • Phenobarbitone, IV or oral. ○ 4 mg/kg/day beginning 12–24 hours after the loading dose.	• Levetiracetam, oral, 40-60mg/kg/dose (Maximum dose 4500mg). ○ Loading dose: 40 mg/kg IV. ○ Second loading dose: 20 mg/kg IV if required. ○ Maintenance: 40–60 mg/kg/day IV or orally 12 hourly.
Paediatric Hospital Level	Chapter 19 Prematurity and Neonatal Conditions	Neonatal Abstinence Syndrome (NAS)	**Opiate withdrawal** • Morphine sulphate ○ 40 mcg/kg/dose 4 hourly. ○ Increase dose 20–40 mcg/kg/dose 8 hourly until symptoms controlled. ○ Maximum dose: 100 mcg/kg/dose. (Addition of phenobarbitone may reduce symptom severity.)	• Phenobarbital, IVI ○ Initially 20 mg/kg, then (by slow intravenous injection) 2.5–5 mg/kg once daily, adjusted according to response.

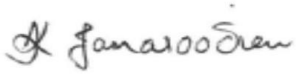
Level of Care	Chapter	Indication	Current Standard Treatment Guideline Recommendation	Alternative During Phenobarbital 30mg Tablet Stock Shortage
			Non-opiate Withdrawal • Phenobarbitone ○ 20 mg/kg, orally, loading dose. ○ Maintenance dose 24 hours later. ○ 4 mg/kg daily in 2 divided doses. **Seizure management** Any seizures should be fully investigated: Refer to section 19.6.2: Seizures, neonatal. • Phenobarbitone ○ 20 mg/kg, orally, loading dose. ○ Maintenance dose 24 hours later. ○ 4 mg/kg daily in 2 divided doses. For opioid withdrawal: • Morphine sulphate (for opiate withdrawal) 100 mcg/kg stat dose, oral/IV, according to clinical status. If on maintenance morphine sulphate, consider increasing dose.	
Paediatric Hospital Level	Chapter 21 Palliative Care	Neuropsychiatric Symptoms Dermatological Symptoms Pruritus Due To Cholestasis (Palliative Care)	• Phenobarbitone	• Cholestyramine, oral, 240 mg/kg/day in 3 divided doses with meals. ○ Mix with water or other fluids. ○ Other medications should be given 1 hour before or 4–6 hours after cholestyramine use. **OR** **Specialist guidance for consideration of:** Rifampicin **OR** Gabapentin

Circular implementation and dissemination

Provinces and facilities are reminded to ensure equitable and timely access as per the paediatric hospital and primary health care STGs and EML, above, and to facilitate availability.

Provinces and healthcare facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees and all other relevant stakeholders.

Kind regards



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