

**SAFETY AND QUALITY
REMINDER OF BEST PRACTICE GUIDANCE**

Subject	Phenobarbital elixir contains a high level of alcohol. It is not recommended for use in children.
HSCB reference number	SQR-SAI-2019-054 (AS/MCH/PHC)
Programme of care	Acute Services; Maternity and Child Health; Primary Health Care

LEARNING SOURCE			
SAI/Early Alert/ Adverse incident	✓	Complaint	
Audit or other review		Coroner's inquest	
Other (Please specify)			

SUMMARY OF EVENT
<p>A 3 year old child was admitted to hospital with increased lethargy, drowsiness and a smell of alcohol on their breath. The child's phenobarbital levels were also noted to be raised, likely as a result of the formulation of phenobarbital the child was taking.</p> <p>The child had been taking phenobarbital 15mg/5ml elixir prior to admission. Although this is licensed in children, and has been for many years, it contains a level of alcohol (38% v/v) that is now considered clinically unsuitable, particularly in young children.</p> <p>Within the hospital, a 'special' phenobarbital 50mg/5ml oral solution is purchased for use in paediatric patients, which does not contain alcohol. This information was not conveyed in the previous discharge letter. The licensed alcohol containing product was subsequently prescribed and supplied in Primary Care.</p>

REQUIREMENTS UNDER CURRENT GUIDANCE

Phenobarbital in children:

Phenobarbital Elixir 15mg/5ml is licensed in children however it contains a level of alcohol that makes it clinically unsuitable, particularly in young children. A number of references provide relevant information on this:

- The [Evelina Children's Hospital Formulary](#)¹ states 'Phenobarbitone liquid B.P contains 38% alcohol, and is very bitter. **Not to be used in children.**'
- The [Royal College of Paediatrics and Child Health \(RCPCH\) and Neonatal & Paediatric Pharmacist Group \(NPPG\)](#)² recommend that when phenobarbital liquid is required, the 50mg/5ml alcohol free preparation is used.
- The BNF for Children advises that 'Some hospitals supply alcohol-free formulations of varying phenobarbital strengths. Different formulations of oral preparations may vary in bioavailability. **Patients should be maintained on a specific manufacturer's product.**'

ACTION REQUIRED

HSC Trusts, GP Practices and Community Pharmacy




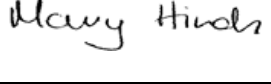
1. Share this Learning Letter with all relevant staff
2. Do not use phenobarbital 15mg/5ml elixir in paediatric patients

For **new** paediatric patients prescribe and supply phenobarbital 50mg/5ml solution (alcohol-free/unlicensed 'special')*. This should be specified on discharge and outpatient letters.

For **existing** patients taking the alcohol containing phenobarbital 15mg/5ml elixir discuss a **managed switch** to phenobarbital 50mg/5ml solution with their secondary care consultant urgently, noting that a different formulation will have different bioavailability.

Patients already taking an alcohol-free preparation but of a different strength do not need to be changed and can be maintained on their current product until review.

**For information, the BHSCT Royal Belfast Hospital for Sick Children currently purchases phenobarbital oral solution 50mg in 5ml (alcohol free) from Huddersfield Pharmacy Specials; other suppliers are available.*

Date issued	18 September 2019			
Signed:				
Issued by	Dr A Mairs Acting Director of Public Health	Mr J Brogan, Head of Pharmacy and Medicines Management	PP Dr M O'Brien Head of GMS	Mrs M Hinds Director of Nursing, Midwifery and Allied Health Professionals

RE: Phenobarbital elixir contains a high level of alcohol. It is not recommended for use in children – Distribution List

	To – for Action	Copy		To – for Action	Copy
HSC Trusts			PHA		
CEXs	✓		CEX		
Medical Director		✓	Medical Director/Director of Public Health		
Directors of Nursing		✓	Director of Nursing/AHPs		
Directors of Social Services			PHA Duty Room		
Governance Leads		✓	AD Health Protection		
Directors of Acute Services		✓	AD Service Development/Screening		
Directors of Community/Elderly Services			AD Health Improvement		
Heads of Pharmacy	✓		AD Nursing		
Allied Health Professional Leads			AD Allied Health Professionals		
Directors of Human Resources			Clinical Director Safety Forum		
NIAS			HSCB		
CEX			CEX		
Medical Director			Director of Integrated Care	✓	
RQIA			Director of Social Services		
CEX			Director of Commissioning		
Director of Quality Improvement			Alerts Office		✓
Director of Quality Assurance			Dir PMSI & Corporate Services		
NIMDTA			Primary Care (through Integrated Care)		
CEX / PG Dean		✓	GPs	✓	
QUB			Community Pharmacists	✓	
Dean of Medical School			Dentists		
Head of Nursing School			BSO		
Head of Social Work School			Chief Executive		
Head of Pharmacy School		✓	Director of Human Resources		
Head of Dentistry School			Head of Procurement		
UU			DoH		
Head of Nursing School			CMO office		
Head of Social Work School			CNO office		
Head of Pharmacy School		✓	CPO office		✓
Head of School of Health Sciences (AHP Lead)			CSSO office		
Open University			CDO office		
Head of Nursing Branch			Safety, Quality & Standards Office		✓
Clinical Education Centre			NI Social Care Council		
NIPEC			Safeguarding Board NI		
NICPLD		✓	NICE Implementation Facilitator		
NI Medicines Governance Team Leader for Secondary Care		✓	Coroners Service for Northern Ireland		