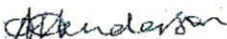


Protocol For The Administration Of Phosphate Enema By Nurses Working Within NHS Grampian To Individuals Prior To Undergoing Bowel Investigations

Lead Author: Senior Charge Nurse	Consultation Group: See relevant page in the Protocol	Approver: Medicines Guidelines and Policies Group
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Signature: 		Signature: 
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NHSG Identifier: MGPG/Protocol/PhosEn/1568	Review Date: October 2026 Expiry Date: October 2027	Date Approved: October 2024
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NHS Grampian have authorised this protocol to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Protocol cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of previous superseded protocol	NHSG/Protocol/PhosEn/MGPG1203, Version 1	
Date of change	Summary of Changes	Section heading
August 2024	Change to section 4.8 undesirable effect – how to report a side effect in SmPC.	Advice (Written)
August 2024	New SmPC.	Advice (Written)

NoS Identifier: MGPG/Protocol/PhosEn/1568
Keyword(s): Protocol administration phosphate enema bowel preparation endoscopy investigations nurses flexible sigmoidoscopy


Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this protocol and to ensure that staff are working to the most up to date protocol. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this protocol act within their own level of competence.

The lead author is responsible for the review of this protocol and for ensuring the protocol is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review and subsequent expiry date should not be more than 3 years from the date the protocol was authorised.

Document: Drafted: August 2024
 Completed: September 2024
 Approved: October 2024
 Amended:

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		07/11/2024

Management and Monitoring of Protocol

Consultative Group

Name:

Title:

Angela Henderson
Evelyn Finn
Laura Sales
Dr Sandeep Siddhi

Lead Author: Senior Charge Nurse
Clinical Pharmacist, Gastroenterology
Nurse Endoscopist, ARI
Consultant Gastroenterologist and Endoscopy Lead, ARI

Protocol For The Administration Of Phosphate Enema By Nurses Working Within NHS Grampian To Individuals Prior To Undergoing Bowel Investigations

Clinical indication to which this Protocol applies

<p>Definition of situation/Condition</p>	<p>This protocol will authorise nurses to administer phosphate enema to individuals aged 16 years and above in order to evacuate and clean the bowel prior to undergoing bowel investigations.</p> <p>This protocol should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).</p>
<p>Inclusion criteria</p>	<p>All individuals aged 16 years and above attending for bowel investigations and who have not had an oral bowel preparation.</p> <p>Prior to the administration of the medicine, valid consent to receiving treatment under this protocol must be obtained. Consent must be in line with current NHSG consent policy.</p>
<p>Exclusion criteria</p>	<p>Individuals may be administered phosphate enema under this protocol unless they:</p> <ul style="list-style-type: none"> • Are under 16 years of age • Have known sensitivity to the product or any of its excipients • Have known active inflammatory bowel disease such as Crohn’s disease or Ulcerative Colitis • Have acute gastro-intestinal conditions, including undiagnosed profuse rectal bleeding; symptoms suggestive of appendicitis or intestinal perforation • Have nausea, vomiting or new or sudden onset of abdominal pain • Have conditions causing decreased gastro-intestinal motility, e.g. known or suspected intestinal obstruction, paralytic ileus, anorectal stenosis, imperforate anus, congenital or acquired megacolon, Hirschsprung’s disease • Are dehydrated and generally in all cases where absorption capacity is increased or elimination capacity is decreased • Have congestive heart failure • Severe renal failure • Are pregnant or breastfeeding • Have not provided valid consent.

Precautions and special warnings

Use with caution in individuals with abnormal renal function, ascites, cirrhosis and uncontrolled hypertension.

Verbally check allergies and previous usage of the preparation with the individual. Do not use where there has been a previous allergic reaction. Check the individuals' records for any documentary evidence regarding previous usage and any adverse reactions.

Use with caution in frail/elderly individuals and those with known electrolyte disturbances or reduced sodium intake.

Use with caution in those taking medications known to prolong the QT interval such as:

- Amiodarone
- Astemizole
- Azithromycin
- Chlorpromazine
- Cisapride
- Citalopram
- Clarithromycin
- Domperidone
- Erythromycin
- Procainamide
- Terfenadine.

Caution should be exercised in individuals with a colostomy who are taking diuretics or other medications which may affect electrolyte levels.

Use with caution in individuals taking calcium channel blockers, ACE inhibitors, angiotensin receptor blockers, diuretics, lithium treatment or other medications that might affect electrolyte levels as hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemic dehydration and acidosis may occur.

No other sodium phosphate preparations including sodium phosphate oral solution or tablets should be given concomitantly.

As hypernatraemia is associated with lower lithium levels, concomitant use of Cleen[®] and Fleet[®] Ready-to-Use Enema and lithium therapy could lead to a fall in serum lithium levels with a lessening of effectiveness.

In cases of rectal bleeding or failure in bowel evacuation after use - seek medical advice immediately.

Action if excluded from treatment	<p>Medical advice must be sought – refer to relevant medical practitioner.</p> <p>Document the reason for exclusion under the protocol and any action taken in the individual's appropriate clinical records.</p>
Action if treatment is declined	<p>Inform/refer to the relevant medical practitioner if individual declines treatment.</p> <p>Document that the administration was declined, the reason and advice given in appropriate clinical records.</p>

Description of treatment available under the protocol

Name form and strength of medicine	<p>Phosphates Enema BP (Formula B) and brand name Cleen[®] ready-to-use enema.</p> <p>Phosphates Enema BP (Formula B): Each 128mL dose delivers Sodium Dihydrogen Phosphate Dihydrate 10% w/v and Disodium Phosphate Dodecahydrate 8% w/v.</p> <p>Cleen[®] Enema: 118mL dose in 133mL bottle delivers the equivalent of 21.4g (18.1% w/v) Sodium Dihydrogen Phosphate Dihydrate and 9.4g (8.0% w/v) Disodium Phosphate Dodecahydrate. Contains 4.4 g sodium per 118mL delivered dose. Also contains 80mg benzalkonium chloride per 118mL delivered dose.</p>
Legal status	Phosphate Enemas are Pharmacy Medicines (P).
Dosage/Maximum total dose	Administer one pre-filled tube only.
Frequency of dose/Duration of treatment	Once only dose.
Maximum or minimum treatment period	N/A
Route/Method of administration	<p>For rectal use only:</p> <ul style="list-style-type: none"> • The enema may be administered at room temperature • Ask the individual to lie on left side with both knees bent, arms at rest

	<ul style="list-style-type: none"> • Remove protective shield • With steady pressure, gently insert enema comfort tip into anus with nozzle pointing towards navel • Squeeze bottle until nearly all liquid is expelled • Discontinue use if resistance is encountered. Forcing the enema can result in injury • Gently remove nozzle from rectum, it is normal to experience some leakage of the enema liquid • Return enema to carton for disposal. <p>Generally, 2 to 5 minutes are sufficient to obtain the desired effect. If delayed discontinue further use and consult a relevant medical practitioner.</p>
Quantity to be administered	One of either Phosphates Enema BP (Formula B) 128mL or Cleen® Enema 118mL.
Storage requirements	Do not store above 25°C. Do not refrigerate
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the medicine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	Advise individual what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	<ul style="list-style-type: none"> • Local irritation. • Rarely, vasovagal attacks have occurred especially in elderly individuals. • Suspected adverse effects should be documented within the individuals care pathway, and reported to medical staff.

	<p>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</p> <p>BNF/BNFC: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE</p> <p>SmPC/PIL/Risk Minimisation Material: Home - electronic medicines compendium (emc) MHRA Products Home RMM Directory - (emc)</p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA</p>
<p>Facilities and supplies required</p>	<p>The following are to be available at sites where the medicine is to be administered:</p> <ul style="list-style-type: none"> • Appropriate storage facilities • An acceptable level of privacy to respect individual’s right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current protocol in print or electronically.

Characteristics of staff authorised to administer medicine(s) under this protocol

<p>Professional qualifications</p>	<p>Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).</p>
<p>Specialist competencies</p>	<p>Approved by the organisation as:</p> <ul style="list-style-type: none"> • Competent to assess the individuals capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent

	<ul style="list-style-type: none"> • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the protocol • Competent to undertake administration of the medicine • Competent to work under this protocol.
Ongoing training and competency	<p>All professionals working under this protocol must:</p> <ul style="list-style-type: none"> • Have undertaken basic life support training in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; <ul style="list-style-type: none"> ○ SmPC for the medicine(s) to be administered in accordance with this protocol.
Responsibilities of professional manager(s)	<p>Professional manager(s) will be responsible for;</p> <p>Ensuring that the current protocol is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this protocol and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the medicine(s) specified in this protocol.</p>

Documentation

Authorisation of administration	<p>Nurses working within NHS Grampian can be authorised to administer the medicine(s) specified in this protocol by their Senior Charge Nurse; Consultant; Nurse Endoscopist or Practice Education Facilitator.</p> <p>All authorised staff are required to read the protocol and sign the Agreement to Administer Medicines Under Protocol (Appendix 1).</p> <p>A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.</p>
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<p>Record of administration</p>	<p>An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this protocol must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> • Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this protocol was obtained • The name, dose, form, route of the medicine administered • Advice given, including advice given if excluded or declined treatment under this protocol • Signature and name in capital letters of the healthcare professional who administered the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). <p>Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:</p> <ul style="list-style-type: none"> • Secondary Care Medical Notes • Individual service specific systems. • Hospital Electronic Prescribing & Medicines Administration (HEPMA) system.
<p>Audit</p>	<p>All records of the medicine(s) specified in this protocol will be filed with the normal records of medicines in each practice/service.</p>
<p>References</p>	<p>Electronic Medicines Compendium Home - electronic medicines compendium (emc) Cleen® Ready-to-Use Enema. Date of revision of text 01/06/22, accessed 08/08/24.</p> <p>Medicines and Healthcare Products Regulatory Agency (MHRA) MHRA Products Home</p> <p>Fletchers' Phosphate Enema (Phosphates Enema BP Formula B) Date of revision of text 15/06/23, accessed 08/08/24.</p> <p>British National Formulary and British National Formulary for Children https://about.medicinescomplete.com/ accessed 08/08/24.</p>



Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Protocol

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Protocol

Protocol For The Administration Of Phosphate Enema By Nurses Working Within NHS Grampian To Individuals Prior To Undergoing Bowel Investigations, Version 2

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above protocol. I agree not to act beyond my professional competence, nor out with the recommendations of the protocol.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Protocol

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this protocol is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this protocol is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this protocol is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

Protocol For The Administration Of Phosphate Enema By Nurses Working Within NHS Grampian To Individuals Prior To Undergoing Bowel Investigations, Version 2

Local clinical area(s) where the listed healthcare professionals will operate under this protocol:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Protocol For The Administration Of Phosphate Enema By Nurses Working Within NHS Grampian To Individuals Prior To Undergoing Bowel Investigations, Version 2

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date