NHS Grampian

Protocol For The Administration Of Medicines As Included In The Formulary Of Nursing Care Products By Nurses Working In Community Hospitals And In The Community Within NHS Grampian

Author:	Consultation Group:	Approver:
Operational Lead Nurse	Page 2	Medicines Guidelines and Polices Group

Signature:		Signature:
CNoble		

Identifier:	Review Date:	Date Approved:
MGPG/Protocol/NursesF/ 1513	October 2027	October 2024

Policy Statement:

It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 2

Executive Sign-Off

This document has been endorsed by Director of Pharmacy and Medicines Management

Signature: _____

Revision History:

Protocol that has been superseded	NHSG/Protocol/NursesF/MGPG1162 Version 1.3	
Revision Date	**Summary of Changes**	**Changes Made**
May 2024	Volume of Phosphate enema corrected to reflect SmPC from 128mL to 118mL.	Phosphate Enema monograph
May 2024	Formula B phosphate enema removed and Cleen® enema added.	Phosphate Enema monograph
May 2024	Exclusion criteria updated.	Phosphate Enema monograph
May 2024	Further information added from Cleen® enema SmPC.	Route/Method of Administration
May 2024	Volume of Phosphate enema corrected to reflect SmPC from 128mL to 118mL.	Phosphate Enema monograph
May 2024	Formula B phosphate enema removed and Cleen® enema added.	Phosphate Enema monograph
June 2024	Section updated from Cleen® enema SmPC.	Potential Adverse Reactions
June 2024	Formula B removed and replaced with Cleen®.	NHS Grampian Formulary of Nursing Care Products Index
Sept 2024	Chloraprep – now only to include 3mL product.	Dose/Maximum Total Dose
Sept 2024	Micolette changed to Microlax.	Sodium Citrate Micro Enema
Sept 2024	Section updated from Cleen® enema SmPC.	Potential Adverse Reactions

NoS Identifier: MGPG/Protocol/NursesF/1513
Keyword(s): Protocol medicines formulary nursing care community hospitals chloraprep glycerol suppositories instillagel lubricating jelly phosphate enema cleen sodium citrate chloride uro trainer

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:	March 2024
	Completed:	May 2024
	Approved:	October 2024
	Amended and re-authorised:	

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	**Signature**	**Date Signed**
Lesley Coyle		31/10/2024

Management and Monitoring of Protocol

Consultative Group

Name:	**Title:**
Katie Anderson	SCN Donbank Ward
Jon Blake	GP, Aberdeenshire
Cheryl Coulson	Lead Nurse Bladder and Bowel Service
Kay Duncan	Lead Nurse Aberdeenshire
Catherine Noble	Lead Nurse Aberdeenshire
Irene Thomson	SCN Aberdeenshire

Protocol For The Administration Of Medicines As Included In The Formulary Of Nursing Care Products By Nurses Working In Community Hospitals And In The Community Within NHS Grampian

Clinical indication to which this Protocol applies

Definition of situation/Condition	This protocol will authorise nurses to administer medications included in the Formulary Of Nursing Care Products (Appendix 3) to individuals aged 16 years and over. 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).
Inclusion criteria	Individuals aged 16 years and over in community hospitals and in the community setting within NHS Grampian. 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.
Exclusion criteria	• Individuals under 16 years of age. • Individuals with specific contra-indications to the use of the required medicine(s) listed in the product monograph (see Appendix 3). • Individuals who have had a previous adverse reaction to the medicine or its excipients. • For additional contraindications please see individual product monographs. • Where there is no valid consent.
Precautions and special warnings	See individual medicine monograph.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the protocol and any action taken in the individual's appropriate clinical records.

Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the protocol

Name form and strength of medicine	See individual medicine monograph.
Legal status	Medicines referred to in this protocol are all either GSL (General Sales List) or P (Pharmacy only) medicines.
Dosage/Maximum total dose	See individual medicine monograph.
Frequency of dose/Duration of treatment	See individual medicine monograph.
Maximum or minimum treatment period	See individual medicine monograph.
Route/Method of administration	See individual medicine monograph.
Quantity to be administered	See individual medicine monograph.
Storage requirements	See individual medicine monograph.
Follow-up (if applicable)	Individuals should be observed for signs of hypersensitivity.
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	See individual medicine monograph. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - medicines starting with A - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at hospital sites where the medicine is to be administered and with the exception of adequate storage facilities, as far as possible when administration is taking place within the community the following should be available: • Appropriate storage facilities where the medicines are kept • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway) • 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

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).

Specialist competencies	**Approved by the organisation as:** • Competent to assess the individuals capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent • 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 supply/administration of the medicine • Competent to work under this protocol.
Ongoing training and competency	**All professionals working under this protocol must:** • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training (or equivalent) which covers all aspects of the identification and management of anaphylaxis updated in-line with 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; ○ SmPC for the medicine(s) to be administered in accordance with this protocol.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current protocol is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this protocol and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this protocol.

Documentation

Authorisation of administration	Nurses working in community hospitals or in the community within NHS Grampian can be authorised to administer the medicine(s) specified in this protocol by their Professional Line Manager or Practice GPs.

	All authorised staff are required to read the protocol and sign the Agreement to Administer Medicines Under Protocol (Appendix 1). 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.
Record of administration	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: • 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 (batch number, expiry date and site where appropriate for injectable medicines) 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). 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: • Individual's GP records if appropriate • Medical Notes • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this protocol will be filed with the normal records of medicines in each practice/service.

References

Electronic Medicines Compendium
http://www.medicines.org.uk

Medicine	Date of Revision	Date Accessed
Chlorhexidine Gluconate 2% & Isopropyl 70% 3mL Applicators (ChloraPrep®)	01/06/2024	12/09/2024
Glycerin (Adult) 4g Suppositories	02/01/2015	12/09/2024
Phosphate Enema (Cleen Ready-to-use®)	01/02/2022	12/09/2024
Sodium Citrate (Rectal) Micro-Enema (Micralax Micro-enema®)	18/10/2021	12/09/2024
Instillagel® 2% Gel	18/02/2019	12/09/2024

Medicines and Healthcare Products Regulatory Agency
http://www.mhra.gov.uk/spc-pil/index.htm

GB-EN-110881E-AQUAGEL.PDF (ecolab.com) Accessed 12/09/2024

Normasol Sterile Topical Irrigation Solution information available from https://www.molnlycke.co.uk/products-solutions/normasol/ Accessed 13/09/2024.

Uro-Tainer® Twin SOLUTIO R Date Sheet and Instructions for use available from https://www.bbraun.co.uk Accessed 13/09/2024.

Uro-Tainer® Suby G Data Sheet and Instructions for use available from https://www.bbraun.co.uk Accessed 13/09/2024.

Sodium Chloride (Uro-Tainer®) 0.9% Irrigation https://www.bbraun.co.uk Accessed 13/09/2024.

British National Formulary and British National Formulary for Children https://about.medicinescomplete.com/ accessed 12/09/2024.

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 Medicines As Included In The Formulary Of Nursing Care Products By Nurses Working In Community Hospitals And In The Community Within NHS Grampian, 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 he or she is 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 he or she understands and is 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 his or her individual code of professional practice and conduct.
Protocol For The Administration Of Medicines As Included In The Formulary Of Nursing Care Products By Nurses Working In Community Hospitals And In The Community Within NHS Grampian – 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 Medicines As Included In The Formulary Of Nursing Care Products By Nurses Working In Community Hospitals And In The Community Within NHS Grampian – Version 2					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

NHS Grampian Formulary of Nursing Care Products

The information in these monographs is not exhaustive. They must be read in conjunction with the current issue of the British National Formulary, and the Summary of Product Characteristics for each product.

<table>
<tr><th colspan="2">ChloraPrep® 2% Cutaneous Solution (Administration)</th></tr>
<tr><td>Indication</td><td>The medicinal product is to be used for disinfection of the skin prior to invasive medical procedures.</td></tr>
<tr><td>Inclusion Criteria</td><td>As per main protocol inclusion criteria.</td></tr>
<tr><td>Exclusion Criteria</td><td>As per main protocol exclusion criteria and additionally:

• Known hypersensitivity to ChloraPrep® or any of its components, especially in those with a history of possible chlorhexidine related allergic reactions.</td></tr>
<tr><td>Precautions and Special Warnings</td><td>Where occlusive dressings are to be applied to areas previously exposed to ChloraPrep® care must be taken to ensure no excess product is present prior to application of the dressing.

The solution is an irritant to eyes and mucous membranes. It should therefore be kept away from these areas. If the solution comes in contact with the eyes, they should be washed promptly and thoroughly with water.

Do not use on open skin wounds. Do not use on broken or damaged skin. In addition, direct contact with neural tissue or the middle ear must be avoided.</td></tr>
<tr><td>Legal Status</td><td>GSL</td></tr>
<tr><td>Dose/Maximum total dose</td><td>
<table>
<tr><th>Applicator</th><th>Coverage Area (cm x cm)</th><th>For Procedures such as:</th></tr>
<tr><td>3mL  </td><td>15 x 15</td><td>• Midline and Central Venous Catheter (CVC) insertion and maintenance
• Peritoneal dialysis site cleansing</td></tr>
</table>
</td></tr>
<tr><td>Frequency of dose/Duration of treatment</td><td>Once only application.</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>Once only treatment.</td></tr>
</table>

ChloraPrep® 2% Cutaneous Solution (Administration)	
Route/Method of Administration	The applicator is removed from the wrapper and held with the sponge facing downward. The applicator is squeezed gently to break the ampoule containing the antiseptic solution, which is released onto the sponge in a controlled flow. Pinch wings **once only** to activate the applicator and release the antiseptic. The sponge is gently pressed against the patient's skin in order to apply the antiseptic solution. Once the solution is visible on the skin, use gentle back and forth strokes for 30 seconds to prepare the site. The area covered should be allowed to air dry completely. This product is for single use only.
Quantity to be administered	See Dose/Maximum total dose section above.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: The solution is flammable. The most commonly reported adverse reactions reported are associated with application site reactions. These were noted to occur most often within the area of application of the solution (i.e. at the prep site) and very rarely spread. The most commonly reported reactions were non-serious in nature and included application site rash, application site erythema, application site vesicles, application site pain and application site pruritus. When the solution has been applied in an over-vigorous manner to very fragile or sensitive skin or after repeated use, local skin reaction may occur including: erythema or inflammation, itching, dry and/or flaky skin and local application site pain. At the first sign of local skin reaction application of ChloraPrep® should be stopped.
Advice	It is recommended that ChloraPrep® remain on the skin post-procedure to provide continued antimicrobial activity. If removal is necessary, remove with soap and water or alcohol.

ChloraPrep® 2% Cutaneous Solution (Administration)	
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction.
Storage	Flammable. This medicinal product does not require any special temperature storage conditions. Store in the original packaging; applicator is sterile unless seal is broken. Avoid exposure of the container and contents to naked flames during use, storage and disposal.

Glycerol 4g Suppositories (Administration)	
Indication	For the relief of occasional constipation.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria and additionally: • Known hypersensitivity to glycerol • Intestinal obstruction or blockage.
Precautions and Special Warnings	Suppositories must not be taken by mouth, for rectal use only. If the individual has had any recent bowel surgery, confirm with a doctor before administering the suppository.
Legal Status	GSL
Dose/Maximum total dose	One 4g suppository as required.
Frequency of dose/Duration of treatment	Once only application.
Maximum or minimum treatment period	Once only treatment.
Route/Method of Administration	The suppository should be dipped in water before insertion. They are suitable for use by the elderly, dose as above.
Quantity to be administered	One 4mg suppository.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: May cause irritation and occasionally abdominal cramps.
Advice	N/A
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction.
Storage	Store below 25°C in a dry place.

Instillagel® 2% Gel (Administration)	
Indication	Lidocaine antiseptic gel is used topically for the anaesthesia of the urethra in urethral pain or to relieve the discomfort of catheterisation. Helps to reduce the risk of infection and gives lubrication to reduce trauma. Can also be used for insertion of suprapubic catheters.
Inclusion Criteria	As per main protocol inclusion criteria and NHSG catheterisation guidelines Adult Catheterisation Guideline
Exclusion Criteria	As per main protocol exclusion criteria and additionally: • Individuals with known hypersensitivity to the active ingredients (amide-type anaesthetics, chlorhexidine and alkyl hydroxybenzoates) or any of the excipients. • Individuals who have damaged or bleeding mucous membranes because of the risk of systemic absorption of the lidocaine hydrochloride.
Precautions and Special Warnings	Products containing local anaesthetics should also be used with caution in patients with impaired cardiac conditions, hepatic insufficiency and in epileptics.
Legal Status	P 6mL gel contains: Lidocaine Hydrochloride 125.40mg Chlorhexidine Gluconate 3.14mg Methyl Hydroxybenzoate 3.76mg Propyl Hydroxybenzoate 1.5mg. 11mL gel contains: Lidocaine Hydrochloride 230.00mg Chlorhexidine Gluconate 5.75mg Methyl Hydroxybenzoate 6.90mg Propyl Hydroxybenzoate 2.87mg.
Dose/Maximum total dose	The doses below should be used once per procedure. Females: 6mL Males: 6-11mL For suprapubic catheterisation 2-3mL (reviewed by the continence service September 2024).
Frequency of dose/Duration of treatment	Once only application.

Instillagel® 2% Gel (Administration)	
Maximum or minimum treatment period	Once only treatment.
Route/Method of Administration	After the usual cleaning of the external genitalia Instillagel® is instilled into the urethra.
Quantity to be administered	See Dose/Maximum total dose above.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Lidocaine should be used with caution in patients receiving antiarrhythmic drugs. Instillagel® contains: Methyl hydroxybenzoate and propyl hydroxybenzoate, which may cause allergic reactions (possible delayed). Propylene glycol which may cause skin irritation. In spite of the proven wide safety range of Instillagel®, undesirable effects of the local anaesthetic, lidocaine, are possible where there is severe injury to the mucosa and absorption may occur.
Advice	N/A
Follow up (If applicable)	Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction.
Storage	This medicinal product does not require any special storage conditions.

Lubricating Jelly (Administration)	
Indication	Lubricating jelly may be used for lubrication of gloves or instruments prior to rectal or vaginal examination. Suppositories, pessaries and enema catheters may be lubricated to aid insertion. Lubrication will aid the passing of stomach tubes for gastric lavage and flatus tubes.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria.
Precautions and Special Warnings	For external use only, not for oral use.
Legal Status	GSL
Dose/Maximum total dose	Apply a small amount of the jelly to the surface of the glove, instrument or other item for insertion.
Frequency of dose/Duration of treatment	Once only application.
Maximum or minimum treatment period	Once only treatment.
Route/Method of Administration	Topical, rectal or vaginal.
Quantity to be administered	See Dose/Maximum total dose above.
Potential Adverse Reactions	No known side effects.
Advice	N/A
Follow up (If applicable)	N/A
Storage	Store under 25°C.

Phosphate Standard Enema (Cleen® Ready-to-use) (Administration)	
Indication	Routine treatment of constipation.
Inclusion Criteria	As per main protocol inclusion criteria.

Exclusion Criteria	As per main protocol exclusion criteria and additionally;
	
	• Hypersensitivity to active ingredients or to any of the excipients
	• Conditions causing increased absorption capacity or decreased elimination capacity, such as when bowel obstruction or decreased bowel motility is present; e.g.,
	  ○ Suspected intestinal obstruction
	  ○ Paralytic ileus
	  ○ Anorectal stenosis
	  ○ Imperforate anus
	  ○ Congenital or acquired megacolon
	  ○ Hirschsprung's disease
	• Undiagnosed gastrointestinal pathology, e.g. symptoms suggestive of appendicitis, intestinal perforation or active inflammatory bowel disease
	• Undiagnosed rectal bleeding
	• Congestive heart failure
	• Dehydration.

Precautions and Special Warnings	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. Use with caution in individuals requiring a reduced sodium intake and electrolyte balance should be maintained during extended use. Use with caution in individuals with intestinal obstruction. Care should be taken not to use undue force in administration of the enema especially in the elderly or debilitated individuals or those with neurological disorders.
Legal Status	P Each Phosphates Enema BP Cleen® 133mL enema gives a delivered dose of 118mL.
Dose/Maximum total dose	Adults, including the elderly, one enema.
Frequency of dose/Duration of treatment	Once only application.

Phosphate Standard Enema (Cleen® Ready-to-use) (Administration)	
Maximum or minimum treatment period	Once only treatment.
Route/Method of Administration	For rectal administration only. The enema may be administered at room temperature or warmed in water before use. Method of administration: • Lie on left side with both knees bent, arms at rest. • Remove orange protective shield. • With steady pressure, gently insert enema Comfortip 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. • Return enema to carton for disposal. • Generally, 2 to 5 minutes are sufficient to obtain the desired effect.
Quantity to be administered	One enema.
Potential Adverse Reactions	Cleen® Ready-to-Use Enema is well tolerated when used as indicated. However, adverse events possibly associated with the use of Cleen® Ready-to-Use Enema have been infrequently reported. In some cases, adverse events may occur, especially if the enema is misused.
Advice	N/A
Follow up (If applicable)	N/A
Storage	Do not store above 25°C. Do not refrigerate.

Sodium Chloride 0.9% Sachets (Administration)	
Indication	Sodium chloride 0.9% sachets are used for topical irrigations such as cleansing the surface of a wound or as an eye bath. The solution is isotonic and will not cause stinging. Sodium chloride solution is the cleaning agent of choice.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria.
Precautions and Special Warnings	Sodium Chloride 0.9% sachets should be used for irrigation only and must never be given by injection. The contents are sterile until the sachet is open. Once opened the contents should be used immediately, any remaining solution must be discarded.
Legal Status	GSL
Dose/Maximum total dose	Dependant on irrigation requirement.
Frequency of dose/Duration of treatment	Apply as often as necessary to cleanse the area.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Topical. Cleanse a wound with a constant flow of fresh sodium chloride solution.
Quantity to be administered	See Dose/Maximum dose section above.
Potential Adverse Reactions	There are no known or established side effects for Sodium Chloride 0.9% sachets.
Advice	N/A
Follow up (If applicable)	N/A
Storage	Store below 25°C.

Sodium Chloride (Uro-Tainer®) 0.9% Irrigation (Administration)	
Indication	Sodium chloride 0.9% bladder washout is used to clear discarded tissue or blood clots from the bladder and so prevents blockage of indwelling urinary catheters. Use of bladder washout solutions is aimed at reducing discomfort for the patient whilst ensuring the catheter remains patent and uninfected. Bladder washout should only be used as required for this purpose (see below).
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria.
Precautions and Special Warnings	Sodium Chloride 0.9% Uro-Tainer® should be used for irrigation only and must never be given by injection.
Legal Status	GSL
Dose/Maximum total dose	In general, daily use is only indicated for post-operative patients during a short period. Long-term catheterized patients may require to rinse a catheter with Uro-Tainer® 2-3 times a week.
Frequency of dose/Duration of treatment	See the Dose/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Catheter irrigation. The contents are sterile until open. Once opened the contents should be used immediately, any remaining solution must be discarded.
Quantity to be administered	See Dose/Maximum dose section above.
Potential Adverse Reactions	There are no known or established side effects for Sodium Chloride (Uro-Tainer®) 0.9% Irrigation.

Advice	N/A
Follow up (If applicable)	N/A
Storage	Store below 25°C.

Sodium Citrate (Rectal) Micro-Enema (Administration)	
Indication	Micro-Enema is indicated whenever an enema is necessary for chronic and acute constipation in the rectum and sigmoid colon. Also indicated for use in constipation in geriatrics and obstetrics.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria and additionally; • Hypersensitivity to the enema or any of the constituents • Inflammatory or ulcerative bowel disease • Acute gastrointestinal conditions.
Precautions and Special Warnings	Excessive use of micro-enema may cause diarrhoea and fluid loss. In such cases, micro-enema should be discontinued and appropriate therapy instituted.
Legal Status	P Each Microlax Micro-enema® contains; Sodium alkyl sulpho acetate 0.90% w/v; sodium citrate 9.0% w/v
Dose/Maximum total dose	One enema tube or two in severe cases of constipation.
Frequency of dose/Duration of treatment	Once only application.
Maximum or minimum treatment period	Once only treatment.
Route/Method of Administration	For rectal administration only. Lubricate the nozzle with one drop of the contents; insert full length of nozzle into the rectum and squeeze tube until total contents have been administered.
Quantity to be administered	See Dose/Maximum dose section above.
Potential Adverse Reactions	Very occasionally, a slight cramp may occur. Prolonged use may lead to irritation of the anal canal.
Advice	N/A

Sodium Citrate (Rectal) Micro-Enema (Administration)	
Follow up (If applicable)	N/A
Storage	Store below 25°C.

Uro-Tainer® Twin SOLUTIO R (Administration)	
Indication	A 6% citric acid based solution for indwelling urethral and suprapubic catheters to dissolve persistent encrustation. Solutio R is also indicated for unblocking encrusted catheters and to reduce the risk of damage to the urethra during the removal of the catheter.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria and additionally; • Solutio R should not be used in cases of cystitis or other urogenital conditions that can produce haematuria.
Precautions and Special Warnings	This solution is intended for urinary catheter rinsing only, not for intravenous infusion. Use after urinary tract surgery should be evaluated by a medical professional. The solution is not a vehicle for additives. It must not be used for the dissolution of medication.
Legal Status	GSL
Dose/Maximum total dose	A 10 minute instillation (5 minutes for each chamber) once or twice per day to once per week, according to the severity of the case. Any deviation from this is out with the scope of this protocol and would require intervention from a medical professional.
Frequency of dose/Duration of treatment	See the Dose/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Catheter irrigation. This solution is intended for urinary catheter rinsing only, not for intravenous infusion. Instil the solution by gravity feed, avoid force.
Quantity to be administered	See Dose/Maximum dose section above.

Uro-Tainer® Twin SOLUTIO R (Administration)	
Potential Adverse Reactions	The acidity of the Solutio R (pH4) can alter the effect of medication. This should be noted particularly in connection with the treatment of urinary infections with antibiotics.
Advice	N/A
Follow up (If applicable)	N/A
Storage	Store below 25°C.

Uro-Tainer® Suby G (Administration)	
Indication	A 3.23% citric acid based solution for indwelling urethral and suprapubic catheters to dissolve encrustation that could lead to the obstruction of the catheter.
Inclusion Criteria	As per main protocol inclusion criteria.
Exclusion Criteria	As per main protocol exclusion criteria and additionally; • Suby G should not be used in cases of cystitis or other urogenital conditions that can produce haematuria.
Precautions and Special Warnings	Precaution should be taken when performing bladder washout on patients with spinal injuries because of the risk of autonomic dysreflexia. Use after urinary tract surgery should be evaluated by a medical professional. The solution is not a vehicle for additives.
Legal Status	GSL
Dose/Maximum total dose	A 5 minute instillation once or twice per day to once per week. Any deviation from this is out with the scope of this protocol and would require intervention from a medical professional.
Frequency of dose/Duration of treatment	See the Dose/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Catheter irrigation. This solution is intended for urinary catheter rinsing only, not for intravenous infusion.
Quantity to be administered	See Dose/Maximum dose section above.
Potential Adverse Reactions	Citric acid may cause some patients to experience slight irritation and even temporary pain, a burning sensation, or spasms of the bladder. If these effects occur it is recommended to carry out the instillations less frequently, or alternate it with an installation if sodium chloride 0.9%.

Uro-Tainer® Suby G (Administration)	
	If the liquid exits from the urethra during irrigation, the catheter may no longer be in the bladder and the patient may require a new catheter. If the liquid does not flow, the catheter may be kinked in the bladder or it may be blocked and may require changing.
Advice	N/A
Follow up (If applicable)	N/A
Storage	Store in original package, protect from light and do not store above 25°C.