NHS Grampian

Patient Group Direction For The Administration Of Medicines As Included In The Midwives PGD Formulary By Midwives Working In Community Maternity Units Within NHS Grampian

Lead Author: AMH Clinical Pharmacist Morrison	**Consultation Group:** See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NHSG Identifier: MGPG/PGD/MidwivesF /MGPG1417	**Review Date:** October 2025 **Expiry Date:** October 2026	**Date Approved:** October 2023

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 3

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD Supersedes NHSG/PGD/MidwF/MGPG1127, Version 2	
Date of change	**Summary of Changes**	**Section heading**
July 2023	Change to new PGD template and 3 yearly update of PGD.	
July 2023	'Woman' changed to individual throughout as per current PGD guidance	
July 2023	Change to blood pressure level inclusion criteria for labetalol	Labetalol 100mg Tablets Monograph
July 2023	Change to blood pressure level inclusion criteria for Nifedipine	Nifedipine 10mg Modified Release Tablets / Capsules Monograph

NHGS Identifier: NHSG/PGD/MidwivesF/MGPG1417
Keyword(s): PGD Patient Group Direction Midwives national formulary, community hospital benzylpenicillin sodium diazepam dihydrocodeine labetalol nifedipine plasma-lyte zopiclon

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 PGD and to ensure that staff are working to the most up to date PGD. 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 PGD act within their own level of competence.

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

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	July 2023
	Completed:	September 2023
	Approved:	October 2023 (published - October 2023)
	Amended and re-authorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Ashalatha Shetty **Title:** Obstetric Consultant **Contact email:** asha.shetty@nhs.scot **Signature:** Ashalatha Shetty **Date:** 26/10/2023
Senior representative of the professional group who will provide care under the direction	**Name:** Liz Cheung **Title:** Lead Midwife for Maternity and Women Services. **Contact email:** liz.cheung@nhs.scot **Signature:** L Cheung **Date:** 30/10/2023
Lead author	**Name:** Charlotte Morrison **Title :** AMH Clinical Pharmacist **Contact email:** charlotte.morrison@nhs.scot **Signature:** C Morrison **Date:** 26/10/2023
Pharmacist	**Name:** Gemma Whelan **Title :** AMH Clinical Pharmacist **Contact email:** gemma.whelan@nhs.scot **Signature:** G Whelan **Date:** 31/10/23

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		31/10/2023

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and is best practice to have a representative of the professional group who will provide care under the direction.

Name:	Title:
Charlotte Morrison	**Lead Author:** AMH Clinical Pharmacist
Gemma Whelan	**Pharmacist:** AMH Clinical Pharmacist
Dr Ashalatha Shetty	**Medical Practitioner:** Obstetric Consultant
Liz Cheung	**Senior Representative:** Lead Midwife for Maternity and Women services
Katie Colville	Associate Director of Midwifery
Chloe Ellison	Interim North Aberdeenshire Community Midwifery Team Leader
Fiona McDonald	Antimicrobial Pharmacist
Linda Stewart	Interim Inpatient Midwifery Manager

Patient Group Direction For The Administration Of Medicines As Included In The Midwives PGD Formulary By Midwives Working In Community Maternity Units Within NHS Grampian

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise midwives to administer medicines to individuals, as included in the Midwives PGD Formulary (Appendix 3). Midwives may, under the Medicines Act 1968, supply all medicinal products on the General Sale List and Pharmacy List and administer a small range of Prescription-only Medicines (POMs). This PGD identifies POMs which may be administered by midwives in addition to those available to midwives under the exemptions noted above. The formulary contains monographs (Appendix 3) for all products covered by the PGD and should be used in conjunction with the information in the core section of the PGD. This PGD 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	Any pregnant or post-natal individual in a community midwifery led maternity unit within NHS Grampian requiring the administration of any of the medicines as included in the Midwives PGD Formulary (Appendix 3) for the treatment of the condition as outlined in the individual medicine monographs. **Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.** The medicines included in this PGD may only be used for the conditions specified within the individual product monograph recommendation and contraindications.
Exclusion criteria	• Individuals with a known or suspected hypersensitivity to the product or any of its ingredients. • Individuals who have previously experienced an adverse reaction to the medicine. • Individuals who meets any of the exclusion criteria listed in the individual monographs. • Individuals for whom no valid consent has been received.

Precautions and special warnings	The medicines listed in this PGD should only be used for the specific conditions detailed in the monographs. If there is any concern about the appropriate use of the medicine in the specific indications given within the PGD then medical advice should be sought immediately. Precautions listed in the individual monographs should be taken into account - see individual medicine monographs for specific precautions. The medicine patient information leaflet should be consulted to ensure that the individual has not experienced a previous hypersensitivity reaction to any ingredients or excipients.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD 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 PGD

Name form and strength of medicine	See individual medicine monographs.
Legal status	Medicines referred to in this PGD are all POM (Prescription-only Medicines).
Is the use out with the SmPC?	See individual medicine monographs.
Dosage/Maximum total dose	See individual medicine monographs.
Frequency of dose/Duration of treatment	See individual medicine monographs.
Maximum or minimum treatment period	See individual medicine monographs.

Route/Method of administration	See individual medicine monographs.
Quantity to be administered	See individual medicine monographs.
Storage requirements	See individual medicine monographs.
Additional Information	See individual medicine monographs.
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. See individual medicine monographs for specific follow-up advice.
Advice (Verbal)	• Advise the individual what to expect and of the possible side effects and their management. • If serious adverse or persistent effects occur, the individual should be advised to contact their community midwife or local obstetric unit. • Individuals should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
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 monographs. **These lists are 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 - (emc)

	If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Appropriate storage facilities or pharmaceutical refrigerator • 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 PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications	Registered midwives as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's 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 PGD • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent to undertake administration of the medicine

	• Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • 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 in-line with Board requirements • Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD. • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Midwives working in Community Maternity Units within NHS Grampian can be authorised to administer the medicine(s) specified in this PGD by their Professional Line Manager or Consultant. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (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 must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent administration, or not, of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not, of the medicine(s) specified in this PGD. 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 PGD was obtained • The name, dose, form, route (batch number, expiry date and anatomical site where appropriate for injectable medicines) of the medicine(s) administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration of the medicine. • 'In accordance with PGD' should be annotated. • Record of any adverse effects and the actions taken (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: • BadgerNet – Digital Maternity Notes • Individual's GP records if appropriate • Secondary Care Medical Notes • HEPMA • Individual service specific systems Local policy should be followed with respect to sharing information with the individual's General Practitioner.

<table>
<tr><td></td><td>All records should be clear, legible and contemporaneous and in an easily retrievable format.</td></tr>
<tr><td>Audit</td><td>All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</td></tr>
<tr><td>References</td><td>Electronic Medicines Compendium

http://www.medicines.org.uk

<table>
<tr><th>Medicine</th><th>Date of Revision</th><th>Accessed</th></tr>
<tr><td>Benzylpenicillin Sodium 600mg Powder for Injection (Genus Pharmaceuticals brand)</td><td>14/09/2021</td><td>29/06/23</td></tr>
<tr><td>Benzylpenicillin sodium 1200mg Powder for Injection (Genus Pharmaceuticals brand)</td><td>13/09/2021</td><td>29/06/23</td></tr>
<tr><td>Diazepam 10mg Rectal Tubes (Desitin Pharma Ltd brand</td><td>05/10/21</td><td>30/06/23</td></tr>
<tr><td>Labetalol 100mg Tablets (Mylan brand)</td><td>28/03/2022</td><td>30/06/23</td></tr>
<tr><td>Nifedipine 10mg Modified Release Tablets (Nifedipress brand)</td><td>27/02/23</td><td>03/07/23</td></tr>
<tr><td>Plasma-Lyte® 148 (pH 7.4) Solution for Infusion (Baxter Healthcare Ltd)</td><td>12/12/18</td><td>03/07/23</td></tr>
<tr><td>Zopiclone 3.75mg Tablets (Aurobindo Pharma - Milpharm Ltd brand)</td><td>18/02/22</td><td>04/07/23</td></tr>
</table>
</td></tr>
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Medicines & Healthcare products Regulatory Agency
MHRA Products | Home

Medicine	Date of Revision	Accessed
Dihydrocodeine Tablets 30mg (Ennogen IP Ltd brand)	12/01/23	30/06/23

British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 29/06/23

Medusa Injectable medicines guide Medusa Logon page (medusaimg.nhs.uk) accessed 29/06/23

National Institute for Health and Care Excellence
NICE guideline NG133 - Hypertension in pregnancy: diagnosis and management https://www.nice.org.uk/guidance/ng133 accessed 30/06/23

NHS Grampian Guidance Management of Latent Phase of Labour V1 https://scottish.sharepoint.com/sites/GRAM-Guidance/Shared%20Documents/Latent%20Phase%20of%20Labour.pdf accessed 04/07/23

NHS Grampian Guidance Management of Severe Pre-Eclampsia V2
https://scottish.sharepoint.com/sites/GRAM-Guidance/Shared%20Documents/Severe%20Pre-Eclampsia.pdf accessed 30/06/23

NHS Grampian Guidance Antenatal Hypertension V1
https://scottish.sharepoint.com/sites/GRAM-Guidance/Shared%20Documents/Antenatal%20Hypertension.pdf accessed 30/06/23

NHS Grampian Guidance Antenatal Hypertension V1 Group B Streptococcus - Prevention of Early Onset Group B Streptococcus in Neonates.pdf (sharepoint.com) accessed 30/06/23

Scotland National Midwifery formulary Plasma-lyte 148® (PGD) V1 https://obsgynhandbook.nhsggc.org.uk/media/1278/plasma-lyte-148-pgd-v1.pdf accessed 03/07/23

Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

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

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD 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 PGD 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 PGD 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.
Patient Group Direction For The Administration Of Medicines As Included In The Midwives PGD Formulary By Midwives Working In Community Maternity Units Within NHS Grampian
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Medicines As Included In The Midwives PGD Formulary By Midwives Working In Community Maternity Units Within NHS Grampian					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

Midwives PGD Formulary Medicine Monographs

Drug Name **Page No:**

Benzylpenicillin Sodium 600mg and 1200mg Powder for Injection	
Indication	Prophylaxis of early onset neonatal *group B streptococcal* (GBS) infection for individuals in labour. This PGD should be used in conjunction with the NHS Grampian Prevention of Early Onset Neonatal Group B Streptococcal Disease Guideline.

Inclusion Criteria	As per main PGD inclusion criteria and additionally;
	• Individuals in active labour at risk of GBS infection:
	  ○ GBS detected vaginally or rectally during the current pregnancy
	  ○ GBS detected in urine during current pregnancy
	  ○ History of a previous baby who was affected by GBS infection
	  ○ GBS confirmed in a previous pregnancy who have opted to have intrapartum antibiotic cover in current pregnancy.

Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Allergy or hypersensitivity to any penicillin antibiotic including co-amoxiclav, and additionally other beta-lactams, including cephalosporins, or any excipients of the injection. • In impaired renal function, large doses of penicillin can cause cerebral irritation, convulsions and coma. Any individuals with renal impairment requiring treatment should be discussed with the medical team.
Precautions and Special Warnings	Each 600mg benzylpenicillin sodium contains 1.68mmol of sodium. Large doses can cause hypokalaemia and sometimes hypernatraemia – however at the doses used in labour as part of this PGD this is not expected to occur. Skin sensitisation may occur in midwives handling the antibiotic and care should be taken to avoid contact with the substance. Delayed absorption from the intramuscular depot may occur in diabetic individuals. Trace amounts of benzylpenicillin sodium can be found in breastmilk however appropriate to proceed with breastfeeding, not known to be harmful to baby.
Legal Status	Benzylpenicillin Sodium 1200mg Powder for Injection is a Prescription-only Medicine (POM).

Benzylpenicillin Sodium 600mg and 1200mg Powder for Injection	
	Benzylpenicillin Sodium 600mg Powder for Injection is a Prescription-only Medicine (POM).
Dose/Maximum total dose	Give 3g at start of labour and then 1.5g every 4 hours until birth. Can be given by the intravenous or intramuscular route. **Individuals should be made aware that IM injections are likely to be less effective than when given IV.** **Additionally the large volume for injection required to be given via the IM route can cause pain and discomfort to the individual.**
Frequency of dose/Duration of treatment	See Dose/Maximum total dose and Route/Method of Administration sections.
Maximum or minimum treatment period	3g at start of labour and then 1.5g every 4 hours until birth. No more than 6 doses in 24 hours. After 24 hours, seek medical review of ongoing management.
Route/Method of Administration	**Intravenous** **3g loading dose -** reconstitute 2 x 1.2g vials each with 8mL Sodium Chloride 0.9% and also reconstitute 1 x 600mg vial with 4mL Sodium Chloride 0.9%. Withdraw 8mL from each 1.2g vial and 4mL from the 600mg vial (20mL in total, 3g) and add to a 100mL bag of Sodium Chloride 0.9% and give by **IV INFUSION** over 30 minutes. **1.5g follow up doses every 4 hours** - reconstitute 1 x 1.2g vial with 8mL Sodium Chloride 0.9% and also reconstitute 1 x 600mg vial with 4mL Sodium Chloride 0.9%. Withdraw 8mL from the 1.2g vial and 2mL from the 600mg vial (10mL in total, 1.5g). Give the 10mL volume by **SLOW IV injection** over at least 5 minutes. **Intramuscular** **3g loading dose** – reconstitute 5 x 600mg vials each with 1.6mL Water for Injection. This gives a total volume of 8mL. Withdraw the contents from each vial and give by **SLOW IM injection over 2 injection sites** into the upper, outer quadrant of the gluteus maximus or Hochstetler's ventrogluteal field maximum IM injection volume is 5mL for one injection site in these muscle groups.

Benzylpenicillin Sodium 600mg and 1200mg Powder for Injection	
	1.2g vials should not be used for IM administration as the required volume of diluent exceeds maximum advised for this route. **1.5g follow up doses every 4 hours** – reconstitute 3 x 600mg vials each with 2mL Water for Injection. Withdraw 5mL (1.5g) only. Give by **SLOW IM injection** into the upper, outer quadrant of the gluteus maximus or Hochstetler's ventrogluteal field. **Note:** Alternate injection sites for all subsequent IM injections.
Quantity to be administered	See Dose/Maximum total dose and Route/Method of Administration sections.
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 (≥1/100 to <1/10) and does not represent all the medicines known adverse effects: • Diarrhoea • Hypersensitivity • Nausea • Skin reactions • Thrombocytopenia • Vomiting • Fever.
Advice	Please refer to local NHS Grampian Prevention of Early Onset Neonatal Group B Streptococcal Disease guideline for additional monitoring to be carried out on individual and baby.
Follow up (If applicable)	It should be recognised that any individual with a history of allergy, especially to drugs, is more likely to develop a hypersensitivity reaction to penicillin. Individuals should be observed during administration and for 30 minutes after administration and if an allergic reaction occurs the drug should be stopped, if applicable, and appropriate treatment given. Do not administer any further benzylpenicillin sodium doses and seek medical advice.
Storage	Do not store above 25°C. Once reconstituted and prepared for administration use immediately.

Diazepam 10mg Rectal Solution	
Indication	To treat epileptic convulsions.
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Any pregnant or post-natal epileptic individual who is suffering from a convulsion.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Acute respiratory insufficiency. • Sleep apnoea syndrome. • Respiratory depression or pulmonary insufficiency. • Severe hepatic impairment. • Phobic or obsessional states; chronic psychosis, hyperkinesis. • Myasthenia gravis (condition may be exacerbated) • Acute porphyria. • Hypersensitivity to any other benzodiazepine.
Precautions and Special Warnings	Benzodiazepines should be used with extreme caution in individuals with a history of alcohol or drug abuse and concomitant intake of alcohol is not recommended. The sedative effect of diazepam may be enhanced. Diazepam should only be used with particular caution in individuals with renal or hepatic dysfunction, chronic pulmonary insufficiency or organic brain changes, particularly arteriosclerosis. Sedation and respiratory or cardiovascular depression may be enhanced if diazepam is combined with centrally acting drugs such as anaesthetics, analgesics (including opioids), antidepressants, hypnotics, sedating antihistamines, neuroleptics and tranquillisers. Individuals should be monitored closely for signs and symptoms of respiratory depression and sedation with concomitant use. Agents that interfere with metabolism by hepatic enzymes (e.g. erythromycin and isoniazid) may reduce the clearance of benzodiazepines or potentiate their actions. Diazepam rectal solution should not be used concomitantly with disulfiram due to its ethanol content. A reaction may occur as long as two weeks after cessation of disulfiram.

Diazepam 10mg Rectal Solution	
	Diazepam rectal solution contains benzoic acid (E210), sodium benzoate (E211) and propylene glycol which may be mildly irritating to the skin and mucous membranes.
Legal Status	Diazepam 10mg Rectal Solution is a Prescription-only Medicine (POM). The use of diazepam during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Dose/Maximum total dose	Administer the contents of one 10mg rectal tube. Repeat 10mg dose after 10-15 minutes if no cessation of fitting. Summon medical help if fitting doesn't subside after initial dose. **Maximum of two doses (20mg) only allowed under PGD.**
Frequency of dose/Duration of treatment	See Dose/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of Administration	For rectal administration only. Individuals should be in the lateral position. Tear open the foil pack. Unscrew the cap and remove. Insert the tube nozzle completely into the rectum. Hold the tube with the nozzle downwards. The contents of the tube should be completely emptied using firm pressure with the thumb and index finger. To avoid suction, maintain pressure on the empty tube until it is withdrawn from the rectum. Press together the individual's buttocks for a short time.
Quantity to be administered	10mg dose which may be repeated if necessary. Maximum of 20mg.

Diazepam 10mg Rectal Solution	
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 (≥1/100 to <1/10) and very commonly reported adverse effects (≥1/10) and does not represent all the medicines known adverse effects: • Confusion • Ataxia, impaired motor ability, tremor, muscle spasms, sedation and unsteadiness • Drowsiness and fatigue • Headaches • High doses administered during labour may cause hypothermia, hypotonia, irregular foetal heart, moderate respiratory depression and poor suckling in the neonate. If given during labour, monitor the neonate for any adverse effects.
Advice	Advice should be given on what to expect and what to do for major and minor reactions. Individuals should be advised to avoid alcohol for up to 24 hours post administration of diazepam. Individuals treated with Diazepam rectal solution should not drive or operate machines for up to 24 hours post administration as sedation, amnesia, impaired concentration and impaired muscular function may adversely affect their ability. If given close to delivery, monitor infant for adverse effects of the diazepam. Diazepam may be found in breast milk, therefore if given to a breastfeeding individual, the infant should be monitored for any adverse effects. The use of diazepam during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Follow up (If applicable)	If convulsions are not controlled medical advice must be sought immediately as other anticonvulsive measures should be considered.

Diazepam 10mg Rectal Solution	
Storage	Do not store above 25°C. Store in the original package in order to protect from light.

Dihydrocodeine 30mg Tablets	
Indication	To treat moderate to severe pain in either the latent or early induction phase of labour, or postpartum.
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Any pregnant or postnatal individual presenting with moderate to severe pain as described above.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Acute respiratory depression. • Acute asthma attack • Obstructive airways disease. • Acute alcoholism. • Severe hepatic or renal dysfunction. • Head injury or raised intracranial pressure (in addition to the risk of respiratory depression and increased intracranial pressure, may affect papillary and other responses vital for neurological assessment). • Dihydrocodeine is also contraindicated where there is a risk of paralytic ileus, or in acute diarrhoeal conditions such as acute ulcerative colitis or antibiotic associated colitis. • Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose. • Breastfeeding individuals if their baby has respiratory symptoms. • Hypersensitivity to any other opioid analgesic.
Precautions and Special Warnings	The hypotensive, sedative and respiratory depressive effects of alcohol may be enhanced; alcohol should be avoided. Use with caution in individuals with a history of drug abuse. Tolerance to analgesic effects may develop upon repeated administration. Dihydrocodeine should be given in reduced doses or with caution to individuals with asthma and decreased respiratory reserve. Additionally, dihydrocodeine should be given in reduced doses or with caution in individuals with adrenocortical insufficiency, urethral stricture, hypotension, shock, inflammatory or obstructive bowel disorders, myasthenia gravis, hypothyroidism, convulsive disorders, mild/moderate hepatic impairment or mild/moderate renal impairment.

Dihydrocodeine 30mg Tablets	
	Dihydrocodeine may cause the release of histamine and should be administered with caution in individuals with allergic disorders. Opioid analgesics should be avoided in individuals with biliary tract disorders or used in conjunction with an antispasmodic. Dihydrocodeine may delay absorption of mexiletine. Opiates potentiate the effects of CNS depressants, including anxiolytics (e.g. chlordiazepoxide, diazepam), hypnotics (e.g. zopiclone), antipsychotics and tricyclic antidepressants. Concomitant administration of dihydrocodeine with anaesthetics, sodium oxybate or sedating antihistamines may cause increased CNS depression and/or respiratory depression and/or hypotension. If the use of dihydrocodeine is considered essential then great care should be taken in individuals taking MAOIs or within 14 days of stopping MAOIs. Dihydrocodeine has an antagonistic effect on cisapride, metoclopramide and domperidone. Cimetidine may inhibit the metabolism of dihydrocodeine resulting in increased plasma concentrations. Cyclizine may counteract the haemodynamic benefits of opioids.
Legal Status	Dihydrocodeine 30mg Tablets are a Prescription-only Medicine (POM).
Dose/Maximum total dose	Antenatal – Single dose of one 30mg tablet. Postnatal – One 30mg tablet 4 to 6 hourly up to a maximum dose of 180mg in a 24 hour period. **Maximum dose of 180mg in 24 hours only allowed on this PGD.**
Frequency of dose/Duration of treatment	Antenatal administration is one dose only. Postnatal administration is for the duration of the individual's admission.

Dihydrocodeine 30mg Tablets	
Maximum or minimum treatment period	N/A
Route/Method of Administration	For oral administration only.
Quantity to be administered	30mg dose which may be repeated if necessary in postnatal pain 4 to 6 hourly, up to a maximum dose of 180mg in 24 hours.
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 and does not represent all the medicines known adverse effects: • Nausea and vomiting (particularly in initial stages) • Constipation • Dry mouth • Headache • Dizziness • Biliary spasm • Hallucinations/confusion.
Overdose	**In the case of suspected overdose medical advice must be sought immediately.** Toxic doses vary considerably with the individual and regular users may tolerate large doses. The triad of coma, pinpoint pupils and respiratory depression is considered indicative of opioid overdosage with dilatation of the pupils occurring as hypoxia develops. Other opioid overdose symptoms include hypothermia, confusion, convulsions, severe dizziness, severe drowsiness, hypotension, nervousness or restlessness, hallucinations, slow heartbeat, circulatory failure, slow or troubled breathing, severe weakness and convulsions. Conservative management is recommended. In acute overdosage with respiratory depression or coma, the specific opioid antagonist naloxone is indicated, using one of the recommended dosage regimens. The individual should be observed closely.

Dihydrocodeine 30mg Tablets	
Advice	Advice should be given on what to expect and what to do for major and minor reactions. Individual should be advised to avoid alcohol while being treated with dihydrocodeine. Advise individual that dihydrocodeine may cause drowsiness and, if affected, individual should not drive or operate machinery. May cause constipation; advise additional fluids and give dietary advice. Dihydrocodeine may be secreted in breast milk, therefore if given to a breastfeeding individual, the infant should be monitored for any adverse effects. Monitor both individual and baby for signs of side effects.
Follow up (If applicable)	Monitor pain scores regularly. If pain remains uncontrolled medical advice should be sought.
Storage	Do not store above 25°C. Store in the original package in order to protect from light.

Labetalol 100mg Tablets	
Indication	To treat severe hypertension in pregnancy, when rapid control of blood pressure is essential. **Labetalol tablets should be used as first line oral drug of choice when intravenous access is unavailable.**
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Pregnant individuals suffering from severe hypertension with a systolic blood pressure >160mmHg and/or diastolic blood pressure >110mmHg, where there is no intravenous access. This PGD should be used in conjunction with the NHS Grampian Guidance Management of Severe Pre-Eclampsia V2.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Cardiogenic shock. • Uncontrolled, incipient or digitalis refractory heart failure. • Sick sinus syndrome (including sinoatrial block). • Second or third degree heart block. • Prinzmetal's angina. • History of wheezing or asthma. • History of bronchospasm or chronic obstructive airways disease. • Untreated pheochromocytoma. • Metabolic acidosis. • Bradycardia (<45-50 bpm). • Severe peripheral circulatory disturbances. • Some brands of tablets contain lactose. If the tablets contain lactose individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take the tablets. • Some brands of tablets contain sucrose. If the tablets contain sucrose individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take the tablets. **Concomitant use not recommended:** Do not administer to individuals taking verapamil, diltiazem, digoxin and/or amiodarone without seeking medical advice. Beta-adrenoceptor blocking drugs may enhance the negative inotropic and chronotropic actions of verapamil, and to a lesser extent diltiazem. Therefore, concurrent use is not recommended.

Labetalol 100mg Tablets	
	Beta adrenoceptor blockers should not be used in conjunction with digoxin as they may increase auriculo-ventricular conduction time. Do not use with monoamine oxidase inhibitors (except MOA-B inhibitors).
Precautions and Special Warnings	Concomitant use of tricyclic antidepressants, barbiturates, phenothiazines or other antihypertensive agents (e.g. nifedipine) may increase the blood pressure lowering effect of labetalol. Concomitant use of tricyclic antidepressants may increase the incidence of tremor. The central depressant effect of alcohol, analgesics and tricyclic antidepressants is potentiated when used with labetalol. Cimetidine, hydralazine and alcohol may increase the bioavailability of labetalol. Parenteral administration of preparations containing sympathomimetics, such as adrenaline, to individuals taking labetalol, may in rare cases, result in vasoconstriction, hypertension and bradycardia. However labetalol is less likely to cause acute hypertensive reactions than other beta-blockers due to its alpha-blocking activity. Furthermore beta-adrenoceptor blockers may reduce response to adrenaline (epinephrine). Administration of anaesthetic drugs with labetalol may lead to attenuation of the reflex tachycardia and increase the risk of hypotension. Continuation of labetalol reduces the risk of arrhythmia during induction and intubation. The anaesthetist should be informed when the individual is receiving labetalol, and anaesthetic agents which can cause myocardial depression, such as cyclopropane and trichlorethylene, should be avoided. Labetalol may enhance the hypoglycaemic effects of antidiabetic agents and mask the warning signs of hypoglycaemia such as tremor and tachycardia. Particular care should be taken when labetalol is used in individuals with hepatic impairment as these individuals metabolise labetalol more slowly than those without hepatic impairment. Lower doses may be required, discuss with medical staff.

Labetalol 100mg Tablets	
	Caution is advised in individuals with a history of hypersensitivity - may increase sensitivity to allergens and result in more serious hypersensitivity response.
Legal Status	Labetalol 100mg Tablets are a Prescription-only Medicine (POM).
Dose/Maximum total dose	200mg (two x 100mg tablets). **Maximum of one dose (200mg) only allowed under PGD.**
Frequency of dose/Duration of treatment	Once only dose.
Maximum or minimum treatment period	N/A
Route/Method of Administration	For oral administration. Labetalol tablets should be taken with food.
Quantity to be administered	One 200mg dose (two x 100mg tablets).
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 and does not represent all the medicines known adverse effects: • Positive antinuclear antibodies unassociated with disease • Hypersensitivity (rash, pruritus, angioedema and dyspnoea) • Dizziness, tingling sensation in scalp usually transient may occur in a few individuals early in treatment • Raised liver function tests • Difficulty in micturition • Heart failure • Fever.

Labetalol 100mg Tablets	
	Labetalol crosses the placental barrier and the possibility of consequences of alpha and beta adrenoceptor blockade in the foetus and neonate should be borne in mind. Perinatal and neonatal distress (bradycardia, hypotension, respiratory depression, hypoglycaemia, hypothermia) has been rarely reported. Beta-blockers reduce placental perfusion, which may result in intrauterine foetal death, immature and premature deliveries. If given close to delivery, monitor neonate for side-effects of labetalol.
Advice	Advice should be given on what to expect and what to do for major and minor reactions. Monitor the individual's response to treatment to ensure their blood pressure falls. Labetalol is excreted in breast milk in small amounts, therefore if given to a breastfeeding individual, the infant should be monitored for any adverse effects. Adverse events of unknown causality (sudden death syndrome, diarrhoea, hypoglycaemia) have been reported very rarely in breast-fed neonates. Caution should be exercised when labetalol is administered to breast-feeding individuals. Monitor individual to identify any adverse effects for both the individual and the baby.
Follow up (If applicable)	As this PGD only allows one 200mg dose of labetalol tablets to be administered, medical advice must be sought immediately following administration and treatment may be modified according to response.
Storage	Store in a dry place below 25°C. Store in the original package in order to protect from light.

Nifedipine 10mg Modified Release Tablets / Capsules	
Indication	Treatment of severe hypertension in pregnancy, where rapid control of blood pressure is essential. **Nifedipine can be used if there is no intravenous access available and if oral labetalol is unavailable or contraindicated.**
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Pregnant individuals suffering from severe hypertension with a systolic blood pressure >160mmHg and/or diastolic blood pressure >110mmHg, where there is no intravenous access or oral labetalol is unavailable or contraindicated. This PGD should be used in conjunction with the NHS Grampian Severe Pre-eclampsia guideline.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Nifedipine must not be administered to individuals with known hypersensitivity to the active substance, or to other dihydropyridines (e.g. amlodipine) because of the theoretical risk of cross-reactivity, or to any of the excipients. • Nifedipine must not be used in cases of cardiogenic shock, clinically significant aortic stenosis, unstable angina, or during or within 4 weeks of a myocardial infarction. • Nifedipine should not be administered to individuals with acute porphyria. • Nifedipine should not be administered to individuals with Kock pouch • The safety of nifedipine in malignant hypertension has not been established. • Nifedipine should not be administered concomitantly with rifampicin since effective plasma levels of nifedipine may not be achieved owing to enzyme induction. • Some brands of tablets/capsules contain lactose. If the tablets/capsules contain lactose individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take it. • Some brands of tablets/capsules contain sucrose. If the tablets/capsules contain sucrose individuals with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take it.

Nifedipine 10mg Modified Release Tablets / Capsules	
Precautions and Special Warnings	Nifedipine may increase the blood pressure lowering effect of concomitantly administered antihypertensives. When nifedipine is administered with beta-receptor blockers the individual should be carefully monitored, since deterioration of heart failure is also known to develop in isolated cases. Digoxin: The simultaneous administration of nifedipine and digoxin may lead to reduced digoxin clearance and, hence, an increase in the plasma digoxin level. The individual should therefore be subjected to precautionary checks for symptoms of digoxin overdosage and, if necessary, the glycoside dose should be reduced. Quinidine: Co-administration of nifedipine with quinidine may lower plasma quinidine levels, and after discontinuation of nifedipine, a distinct increase in plasma quinidine levels may be observed in individual cases. Consequently, when nifedipine is either additionally administered or discontinued, monitoring of the quinidine plasma concentration, and if necessary, adjustment of the quinidine dose are recommended. Blood pressure should be carefully monitored and, if necessary, the dose of nifedipine should be decreased. Tacrolimus: Tacrolimus is metabolised via the cytochrome P450 3A4 system. Published data indicate that the dose of tacrolimus administered simultaneously with nifedipine may be reduced in individual cases. Upon co-administration of both drugs, the tacrolimus plasma concentrations should be monitored and, if necessary, a reduction in the tacrolimus dose considered. The plasma concentrations of phenytoin, theophylline, non-depolarising muscle relaxants (e.g. tubocurarine) are increased when used in combination with nifedipine. Nifedipine may result in increased levels of mizolastine due to inhibition of cytochrome CYP3A4. Nifedipine may increase the neuromuscular blocking effects of vecuronium.

Nifedipine 10mg Modified Release Tablets / Capsules	
	Nifedipine is metabolised via the cytochrome P450 3A4 system. Upon co-administration with known inhibitors of the cytochrome P450 3A4, plasma nifedipine concentration may be increased. The individual should be discussed with medical staff and should have their blood pressure monitored regularly. If necessary, a reduction of the nifedipine dose should be considered. Examples of drugs within this class include; • macrolide antibiotics (e.g. erythromycin) • anti-HIV protease inhibitors (e.g. ritonavir) • azole antimycotics (e.g. ketoconazole) • fluoxetine/nefazodone • quinupristin/dalfopristin • valproic acid • cimetidine. Grapefruit juice inhibits the cytochrome P450 3A4 system. Administration of nifedipine together with grapefruit juice thus results in elevated plasma concentrations and prolonged action of nifedipine and the blood pressure lowering effect of nifedipine may be increased. After regular intake of grapefruit juice, this effect may last for at least three days after the last ingestion of grapefruit juice. Ingestion of grapefruit/grapefruit juice is therefore to be avoided while taking nifedipine. Increased plasma levels of nifedipine have been reported during concomitant use of alcohol, cyclosporin, gingko biloba and ginseng. Enhanced hypotensive effect of nifedipine may occur with: aldesleukin, alprostadil, anaesthetics, antipsychotics, diuretics, phenothiazides, prazosin and intravenous ionic X-ray contrast medium. Profound hypotension has been reported with nifedipine and intravenous magnesium sulphate in the treatment of pre-eclampsia. Co-administration with known inducers of the cytochrome P450 3A4 system may decrease exposure to nifedipine. Examples of drugs within this class include: • phenytoin • carbamazepine • phenobarbital

Nifedipine 10mg Modified Release Tablets / Capsules	
	Decreased plasma levels of nifedipine have also been reported during concomitant use of St John's Wort. Nifedipine should be used with caution in individuals whose cardiac reserve is poor, and in those with heart failure or significantly impaired left ventricular function. Deterioration of heart failure has occasionally been observed with nifedipine. The use of nifedipine in diabetic individuals may require adjustment of their control. In individuals undergoing dialysis with malignant hypertension and hypovolaemia, a marked decrease in blood pressure can occur. In individuals with mild, moderate or severe impaired liver function, careful monitoring and a dose reduction may be necessary. The pharmacokinetics of nifedipine has not been investigated in individuals with severe hepatic impairment, therefore, nifedipine should be used with caution in individuals with severe hepatic impairment.
Legal Status	Nifedipine 10mg Modified Release Tablets/Capsules are a Prescription-only Medicine (POM). The use of nifedipine during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Dose/Maximum total dose	One 10mg Modified release Tablet/Capsule. **Maximum of one dose (10mg) only allowed under PGD.** Nifedipine 10mg Modified Release tablets/capsules must be documented by brand when administered. Brands vary due to availability; brands include Coracten SR 10mg capsules.
Frequency of dose/Duration of treatment	Once only dose.
Maximum or minimum treatment period	N/A

Nifedipine 10mg Modified Release Tablets / Capsules	
Route/Method of Administration	For oral administration. Modified Release Tablets/Capsules should be swallowed whole with a little liquid, either with or without food. Should not be taken with grapefruit juice.
Quantity to be administered	One 10mg dose.
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 and does not represent all the medicines known adverse effects: • Headache • Oedema (incl. peripheral oedema) • Vasodilatation • Constipation • Malaise From the clinical evidence available a specific prenatal risk has not been identified, although an increase in perinatal asphyxia, caesarean delivery, as well as prematurity and intrauterine growth retardation have been reported. It is unclear whether these reports are due to the underlying hypertension, its treatment, or to a specific drug effect.
Advice	Advice should be given on what to expect and what to do for major and minor reactions. If given close to delivery, monitor neonate for adverse reactions. The use of nifedipine during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Follow up (If applicable)	As this PGD only allows one 10mg dose of nifedipine modified release tablets/capsules to be administered, medical advice must be sought immediately following administration.
Storage	Store at or below 25°C protected from light.

Plasma-Lyte® 148 (pH 7.4) Solution for Infusion	
Please note: The contents of this medicine monograph have been based on the information for Plasma-Lyte® 148 (PGD) as contained in the Scottish National Midwifery Formulary, available from: https://obsgynhandbook.nhsggc.org.uk/media/1278/plasma-lyte-148-pgd-v1.pdf.	
Indications	1) Sudden drop in systolic blood pressure. 2) Replacement of fluid to maintain circulatory volume until blood is available as per local guideline for postpartum haemorrhage.
Inclusion Criteria	As per main PGD inclusion criteria and additionally; • Individuals requiring resuscitation with intravenous fluids including hypotension and haemorrhage.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • individuals with: ○ Extracellular hyperhydration or hypervolaemia ○ Severe renal insufficiency (with oliguria/anuria) ○ Heart block ○ Hyperkalaemia ○ Hypernatraemia ○ Hyperchloraemia ○ Hypermagnesaemia ○ Hypochlorhydria ○ Metabolic or respiratory alkalosis.
Precautions and Special Warnings	Use with caution in individuals with or at risk of hypocalcaemia. Plasma-Lyte contains no calcium and an increase in plasma pH due to alkalinizing effect may lower the concentration of ionized calcium. Use with caution in individuals at risk of: • Hypermagnaesemia, i.e. mild renal impairment, myasthenia gravis, individuals being treated with magnesium sulphate infusions (for eclampsia or pre-term labour) • Hyperkalaemia, particularly individuals with cardiac disease, renal or adrenocortical insufficiency and acute dehydration, or extensive tissue destruction as occurs with severe burns Use with caution in individuals at risk of fluid overload or conditions that cause sodium retention and oedema.

Plasma-Lyte® 148 (pH 7.4) Solution for Infusion	
	Solutions containing sodium should be carefully administered to individuals with hypertension, heart failure, peripheral or pulmonary oedema, impaired renal function, preeclampsia, aldosteronism, or other conditions associated with sodium retention. Must not be infused in the same line as blood. Potential for interactions with the following; • corticosteroids • potassium sparing diuretics • ACE inhibitors, angiotensin –II receptor antagonists • tacrolimus, ciclosporin • digoxin • acidic drugs such as salicylates, barbiturates and lithium • alkaline drugs such as ephedrine and pseudoephedrine. If there is a drug interaction, consult with a doctor/GP before administration or supply. Document consultation in maternity record. Refer to current BNF for latest information on interactions
Legal Status	POM - Midwife may administer in accordance with a PGD.
Dose/Maximum total dose	**Maternal resuscitation (including sudden drop in systolic blood pressure):** 500mL or 1 litre bag to be infused through a 14/16 gauge needle as quickly as possible. Maximum of 2 litres in case of haemorrhage (unless no colloid or blood is available and individual still haemorrhaging - continue until help arrives). If giving for any other reason maximum of 1 litre. Ideally when given rapidly the solution should be warmed to no more than 37°C.
Frequency of dose/Duration of treatment	As above
Maximum or minimum treatment period	As above

Plasma-Lyte® 148 (pH 7.4) Solution for Infusion	
Route/Method of Administration	Intravenous Infusion
Quantity to be administered	As above

Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects.
	
	• Hypersensitivity/infusion reactions:
	  ○ Tachycardia, palpitations
	  ○ Chest pain/discomfort
	  ○ Dyspnoea, increased respiratory rate
	  ○ Flushing, fever
	  ○ Peripheral oedema
	  ○ Urticaria
	  ○ Infusion site reactions: pain, irritation, infection
	• Hypervolaemia
	• Seizures
	• Thrombophlebitis
	• Venous thrombosis.

Overdose	Overuse or too fast administration can lead to water and sodium overload with oedema. Other symptoms due to excess of other ingredients; • Hyperkalaemia - paraesthesia, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. • Hypermagnesaemia - loss of deep tendon reflexes and respiratory depression (both due to neuromuscular blockade), nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilatation, drowsiness, confusion, muscle weakness, bradycardia, coma, and cardiac arrest. • Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect. • Excessive administration of compounds, such as sodium acetate and sodium gluconate, which are metabolised to form the bicarbonate anion may lead to hypokalaemia and metabolic alkalosis, especially in individuals with impaired renal function. Symptoms may include mood changes, tiredness, and shortness of breath, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop especially in

Plasma-Lyte® 148 (pH 7.4) Solution for Infusion	
	hypocalcaemic individuals. Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance. In the case of overdose immediate assessment/ treatment is essential - refer to medical staff. Management should be in accordance with established treatment guidelines or see BNF overdose section. For further advice contact National Poisons Centre 0344 892 0111.
Advice	Referral to medical staff is required.
Follow up (If applicable)	If used for sudden drop in blood pressure or postpartum haemorrhage urgent obstetric and anaesthetic help is required. Monitor serum urea and electrolytes and if for postpartum haemorrhage full blood count and send blood for group and screen. Position individual flat on one side. Monitor pulse and BP.
Storage	Store at room temperature. Use immediately after opening. Use only if the solution is clear, without visible particles and if the container is undamaged.

Zopiclone 3.75mg Tablets	
Indication	To provide sedation during prolonged latent phase (>24 hours) of labour.
Inclusion Criteria	As per main PGD inclusion criteria and additionally; Any pregnant individual requiring sedation during prolonged latent phase (> 24hours) of labour. This PGD should be used in conjunction with the NHS Grampian Management of Latent Phase of Labour guideline.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Less than 18 years of age. • Myasthenia gravis. • Respiratory failure. • Sleep apnoea syndrome. • Severe hepatic insufficiency. • Individuals who have previously experienced complex sleep behaviours after taking zopiclone • Individuals with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as it contains lactose.
Precautions and Special Warnings	As hypnotics have the capacity to depress respiratory drive, precautions should be observed if zopiclone is prescribed to individuals with compromised respiratory function. A lower dose is recommended for individuals with chronic respiratory insufficiency due to the risk of respiratory depression. Medical assessment may be required. In mild/moderate hepatic insufficiency, a maximum dose of 3.75mg is recommended. Benzodiazepines are not indicated to treat individuals with severe hepatic insufficiency as they may precipitate encephalopathy. Concomitant use of zopiclone and opioids may result in sedation, respiratory depression, coma, and death. Because of these risks, concomitant prescribing of sedative medicines such as benzodiazepines or related drugs such as zopiclone with opioids should be reserved for individuals for whom alternative treatment options are not possible.

Zopiclone 3.75mg Tablets	
	In combination with CNS depressants an enhancement of the central depressive effect may occur. The therapeutic effect of co-administration antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant agents, antiepileptic drugs, anaesthetics and sedative antihistamines should therefore be carefully weighed. Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450) may enhance the sedative activity of zopiclone, e.g. ritonavir. A dose reduction for zopiclone may be required when it is co-administered with CYP3A4 inhibitors. Medical assessment may be required. The AUC of zopiclone is increased by 80% in presence of erythromycin which indicates that erythromycin can inhibit the metabolism of drugs metabolised by CYP 3A4. As a consequence, the hypnotic effect of zopiclone may be enhanced. Co-administration with Drugs which induce P450 CYP3A4, like phenobarbital, phenytoin, carbamazepine, rifampicin and products containing St John's wort, may reduce zopiclone plasma levels and thus the effect of zopiclone. A dose increase for zopiclone may be required when it is co-administered with CYP3A4 inducers. Medical assessment may be required. Combination of zopiclone with muscle relaxants may increase the muscle relaxing effect. Metoclopramide increases the concentration of zopiclone in the blood plasma and may result in faster onset of zopiclone action.
Legal Status	Zopiclone 3.75mg Tablets are a Prescription-only Medicine (POM). The use of zopiclone during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Dose/Maximum total dose	One 3.75mg tablet. **Maximum of one dose (3.75mg) only allowed under PGD.**

Zopiclone 3.75mg Tablets	
Frequency of dose/Duration of treatment	One dose.
Maximum or minimum treatment period	N/A
Route/Method of Administration	One 3.75mg dose to given orally during the latent phase of labour only. Each tablet should be swallowed whole without sucking, chewing or breaking the tablet.
Quantity to be administered	3.75mg dose.
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 (≥1/100 to <1/10) and does not represent all the medicines known adverse effects: • Dysgeusia (Bitter taste) • Somnolence • Reduced alertness • Dry mouth. Administration of zopiclone during labour has been associated with effects on the neonate, such as hypothermia, hypotonia, feeding difficulties and respiratory depression. Cases of severe neonatal respiratory depression have been reported.
Advice	Advice should be given on what to expect and what to do for major and minor reactions. Following administration individuals should be advised to avoid driving, using alcohol or engaging in activities requiring alertness. They should be advised to make contact with the maternity unit when there are in established labour. The use of zopiclone during pregnancy is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.

Zopiclone 3.75mg Tablets	
Follow up (If applicable)	Monitor the newborn postnatally for any adverse effects of zopiclone administration during the latent phase of labour.
Storage	Store below 30°C and keep the blister in the outer carton in order to protect from light and moisture.