University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of MEPTAZINOL SOLUTION FOR INJECTION By Registered Midwives in Maternity Services at Queens Hospital Burton

Documentation details

Reference no:	UHDB138
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Change history

Version number	Change details	Date
3	Updated to UHDB format from QHB format	8 JUNE 2021
	Updated ongoing training and competency to include e-learning module.	
	Removed <18 years old from criteria for exclusion	
	Added to section on cautions to avoid mixing with any other drugs in the same syringe. Added advice on support when patients at risk of opioid misuse.	
	Drug interactions updated and interactions identified for each drug from medices.org.uk	
	Added common, uncommon and unknown side effects and neonatal side effects and management.	

Glossary

Abbreviation	Definition
MAOI	monoamine-oxidase inhibitors

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Devjani Das	Obstetric Consultant
Julie Vanes	Senior Pharmacist Medicines Safety / Paediatrics, QHB sites
Sarah Evans	Intrapartum Matron

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Queens Hospital Burton – Maternity Services
Limitations to authorisation
N/A

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist)	**James Hooley**	Signed copy held in Pharmacy	26/09/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Senior Pharmacist Medicines Safety / Paediatrics, QHB sites	**Julie Vanes**	**Signed copy held in Pharmacy**	**19/07/2022**
Obstetric Consulant	**Dr Devjani Das**	**Signed copy held in Pharmacy**	**22/09/2022**
Matron, Intrapartum Care	**Sarah Evans**	**Signed copy held in Pharmacy**	**19/07/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	NMC Registered Midwife
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Midwives are expected to keep themselves updated with the local guidance provided. No additional specific training is required. Competency and registration to be maintained as per NMC and Trusts standards for mandatory and essential to role training.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Moderate to severe pain in obstetric patients in labour.
Criteria for inclusion	Pregnant women in labour.
Criteria for exclusion	• Hypersensitivty to the active substance – Meptazinol. • Acute alcoholism and where there is a risk of paralytic ileus • Raised intracranial pressure or head injury (in addition to interfering with respiration, affect pupillary responses vital for neurological assessment) • Phaeochromocytoma (risk of pressor response to histamine release) • Acute respiratory depression • During an asthma attack • Myocardial infarction • Phaeochromocytoma (tumour of the adrenal glands) • Patients on monoamine-oxidase inhibitors (MAOIs) and for 14 days after discontinuing an MAOI
Cautions including any relevant action to be taken	• Respiratory disease • Renal impairment (dose should be reduced) • Hepatic impairment (dose should be reduced) • Hypotension • Hypothyroidism • Asthma (avoid during an attack) • Convulsive disorders • Meptazinol injection should not be mixed with other drugs in the same syringe. • Additional support and monitoring may be necessary when prescribing for patients at risk of opioid misuse.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment
Arrangements for referral for medical advice	Escalate to Obstetric Registrar/SHO.

5. Description of treatment

Name, strength & formulation of drug	Meptazinol 100mg/ml Solution for injection
Legal category	Prescription Only Medicine (POM)
Route / method of administration	Intramuscular injection
Indicate any off-label use	n/a

(if relevant)	
Dose and frequency of administration	Intramuscular injection: a dose of 100-150mg should be used according to weight. This dose should approximate 2mg/kg (consider reduced dose up to 1mg/kg in renal or liver impairment). The injection may be repeated 2-4 hourly as required.
Duration of treatment	Duration of labour, maximum of 3 doses.
Quantity to be supplied (leave blank if PGD is administration ONLY)	*n/a*
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store below 25°C.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* • Antidepressants: hypertension or hypotension when given to patients who have/are taking MAOIs (including moclobemide) during the previous 14 days. Possible increased sedation if meptazinol is used with tricyclic antidepressants e.g. amitriptyline. • Antipsychotics: enhanced sedative and hypotensive effect. • Antivirals: plasma concentration of meptazinol may be increased. • Alcohol: enhanced sedative and hypotensive effect. • Anxiolytics and hypnotics: enhanced sedative effect. • Drugs used in nausea and vomiting: may result in antagonism of gastrointestinal side-effects. • Ulcer healing drugs: may inhibit metabolism of meptazinol resulting in increased plasma concentration. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	The following side effects are common: • Dizziness • Headache • Vertigo • Somnolence • Drowsiness • Abdominal pain • Constipation • Diarrhoea

	• Dyspepsia • Nausea • Vomiting • Increased sweating • Rash **Uncommon (≥ 1/1,000 to ≤ 1/100)** • Hypotension • Respiratory depression **Unknown (frequency cannot be estimated from the available data)** • None Gastric stasis and inhalation pneumonia has been reported in the mother if opioid analgesics are used in labour. **Neonatal** Administration during labour may cause respiratory depression in the neonate and naloxone should be readily available. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • Respiratory depression caused by over-dosage with meptazinol may only be partially reversed with therapeutic doses of naloxone. Naloxone has a short duration of action in comparison with meptazinol. Repeated administration or administration by continuous intravenous infusion may be considered necessary.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	Inform client of potential to cause: • Nausea, vomiting or drowsiness • Sweating, headache, tachycardia, palpitations, rashes and mood changes • Ask client to inform staff of any difficulty breathing • Administration during labour may cause respiratory depression in the neonate.
Records	The administration of the PGD should be recorded:

	- ePMA (Electronic Prescribing system) UHDB Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ [Accessed 15 June 2021] • Electronic BNF https://bnf.nice.org.uk/ [Accessed 15 June 2021] • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 [Accessed 15 June 2021]

7. Registered health professional authorisation sheet

PGD Name [version]: Maternity – Meptazinol Solution for Injection[v1]
PGD ref: UHDB138

Valid from: 26/09/2022 Expiry date: 25/09/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.