**Template protocol for the administration of omeprazole tablets pre caesarean section by registered midwives for in location/service/organisation**

Version Number 1.0

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| **Change History** | |
| **Version and Date** | **Change details** |
| Version 1  April 2023 | New template |

This template protocol, for local adaptation, has been peer reviewed by the Preventative Medicines in Pregnancy PGDs Short Life Working Group in accordance with their Terms of Reference. It has been reviewed by the Royal College of Obstetrics and Gynaecology (RCOG) in March 2023.

For advice on protocol use in practice/advised supporting governance please refer to [When Patient Group Directions are not required](https://www.sps.nhs.uk/articles/when-patient-group-directions-are-not-required/) and [About the SPS Medicines Governance Do Once Programme](https://www.sps.nhs.uk/articles/about-the-sps-medicines-governance-do-once-programme/)

Each organisation using this protocol must ensure that all clinical content is appropriately reviewed and approved for use in line with the organisations’ guidelines and governance system.

**Protocol development group**

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| Jacqueline Lambert | Professional Advisor Midwifery & Perinatal Care, Chief Nursing Office’s Directorate (CNOD) & Directorate for Children and Families (DCAF), Scottish Government |
| Jo Jenkins (Working and core Group Co-ordinator) | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Karen Todd | Head of Maternity and Neonatal NHS Quality, Safety and Investigations, Department of Health and Social Care |
| Katherine Oldridge | GP Clinical Lead for Bath, Swindon and Wiltshire-NHS Bath and North East Somerset, Swindon and Wiltshire CCG |
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| **1. Staff competencies** | |
| **Authorised staff** | Registered midwives working within [insert name of organisation] |
| **Additional requirements** | *Insert detail as local agreement to include:*   * *staff grade levels as appropriate;* * *requirements of training to be undertaken before accessed as competent;* * *any going training/CPD requirements.* |
| **2. Clinical condition or situation** | |
| **Clinical situation** | Administration of oral omeprazole for the reduction of risk of pulmonary aspiration of gastric contents in individuals prior to planned or emergency caesarean section. |
| **Individuals included (note adapt to reflect local policy – this is an example only):** | * Individual consents to treatment. * Planned caesarean section under regional or general anesthetic. * Individuals in labour who meet one or more of the following criteria and are at risk of requiring a general anaesthetic during the peripartum period:   Maternal factors:   * oxytocin infusion for induction or augmentation of labour * previous lower segment caesarean section (CS) * pre-eclampsia * significant antepartum haemorrhage (APH) * significant PPH with increased risk of needing anaesthesia * epidural analgesia in labour * remifentanil PCA * awaiting transfer to theatre for manual removal of placenta or perineal tear repair   Fetal factors:   * growth-restricted fetus < 2 kg * oligohydramnios (AFI < 5cm) * suspicious or pathological cardiotocograph (CTG) * significant meconium staining of liquor   OR increased anaesthetic risk:   * raised body mass index (BMI >35) * contraindication to regional anaesthesia (e.g. thrombocytopenia, previous back surgery with metalwork) |
| **Individuals excluded (note adapt to reflect local policy – this is an example only):** | * Consent not given * Hypersensitivity to any of the ingredients of the preparation (see SPC [www.medicines.org.uk](http://www.medicines.org.uk)) * Omeprazole, or another proton pump inhibitor already taken within past 12 hours * Concurrently taking any anti-retroviral medications for the treatment/prevention of HIV. |
| **Action for individuals excluded** | Complete with local pathway |
| **Action if individual declines treatment** | Complete with local pathway |
| **3. Description of treatment** | |
| **Medicine to be administered** | Omeprazole 10mg/20mg tablets |
| **Dose schedule (note adapt to reflect local policy – schedule given as an example only):** | * **Planned caesarian section:**   Morning surgery planned: 40mg at 10pm the night before and 40mg at 6am on the morning of the planned caesarean section.  Afternoon surgery planned: 40mg at 6am and 40mg at midday on the morning of the planned caesarean section.   * **Individuals in labour at high risk of an unplanned caesarian section:** 40mg every 12 hours until delivery. |
| **Maximum dosage to be administered under this protocol (note adapt to reflect local policy – maximum dosages given as an example only):** | * **Planned caesarian section:** 2 doses as detailed in dose schedule section. * **Individuals in labour at high risk of an unplanned caesarian section:** 6 doses over 72 hours |
| **Off label use** | The use of omeprazole for the indications detailed within this protocol are outside the product license but are supported by national guidance. |
| **Follow up/individual advice** | * Inform individual of medicine being administered and rationale for administration. * Inform individual of potential adverse effects and how to report these to the clinical team. |
| **Record keeping** | The following must be recorded on the *medicine chart/EPS or clinical notes as per local protocol*:   * Date and time of administration. * Individual’s details such as name, date of birth, hospital or NHS number (where applicable), allergies, previous adverse events and the criteria under which the individual fits the protocol. * Details of medicines including name, strength dose, route. * A statement that administration is under a protocol. * Name and signature (which may be electronic) of healthcare professional acting under the protocol to supply the medication. * Relevant information that was given to the individual/carer. * Record that consent gained (or refused) – if consent refused record actions taken. |
| **References** | NICE guideline Caesarean birth Published: 31 March 2021  <https://www.nice.org.uk/guidance/ng192/resources/caesarean-birth-pdf-66142078788805>  Summary of Product Characteristics: [www.medicines.org.uk](http://www.medicines.org.uk) |