**Template protocol for the supply of omeprazole tablets pre planned caesarean section by registered midwives for local adaptation 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 |
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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** | Supply of oral omeprazole to be taken for the reduction of risk of pulmonary aspiration of gastric contents in individuals prior to admission for planned 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 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 prescribed or being taken by the individual. * 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 tablets/20mg tablets |
| **Dose schedule (note adapt to reflect local policy – schedule given as an example only):** | * Morning surgery planned: 40mg (4x10mg tablets/2x20mg tablets) at 10pm the night before and 40mg (4x10mg tablets/2x20mg tablets) at 6am on the morning of the planned caesarean section. * Afternoon surgery planned: 40mg (4x10mg tablets/2x20mg tablets) at 6am and 40mg(4x10mg tablets/2x20mg tablets) at midday on the morning of the planned caesarean section. |
| **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. |
| **Medicine to be supplied** | Sealed General Sales List (GSL) pack of omeprazole 10mg or 20mg tablets appropriately over labelled to detail dosage schedule to be taken as detailed above or if not over labelled then appropriate written information to support the dosage schedule is provided. |
| **Follow up/individual advice** | * Inform individual of medicine being administered and rationale for administration. * Offer Patient Information Leaflet supplied with the product or locally produced information leaflet if applicable. * 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 supply. * 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 supplied including name, strength dose, route and quantity. * A statement that supply 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**  **(accessed January 2023)** | 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) |