

Surrey & North West Sussex Area Prescribing Committee

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Application for change in colour classification

GREEN - Non-Specialist Drugs

GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiation and continuation of prescribing

BLUE - Specialist Input WITHOUT Formal Shared Care Agreement

Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement

AMBER - Specialist Initiation WITH Shared Care Guidelines

Prescribing initiated and stabilised by specialist but has potential to transfer to primary care under a formal shared care agreement

RED - Specialist ONLY drugs

Treatment initiated and continued by specialist clinicians

BLACK – NOT recommended

Not recommended for use in any health setting across Surrey and NW Sussex health economy

Medicine details¹

Name, brand name	Domperidone (Motilium®)	
Manufacturer	Manufacturer(s) - various	
Licensed indication	Relief of the symptoms of nausea and vomiting only in adults and adolescents 12 years of age or older and weighing 35 kg or more	
Formulation	Oral - standard tablets and oral suspension	
Usual dosage	<p><i>Adults and adolescents (12 years of age and older and weighing 35 kg or more):</i> One 10mg tablet up to three times per day with a maximum dose of 30 mg per day.² Domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week.²</p>	
Traffic Light Status	Current status	Proposed status
	<p>GREEN - For relief of the symptoms of nausea and vomiting in adults and children (<u>including children with body-weight under 35kg</u>)</p>	<ul style="list-style-type: none"> GREEN - For relief of the symptoms of nausea and vomiting <u>only in adults and adolescents 12 years of age or older and weighing 35kg or more.</u> RED - For any indications in children younger than 12 years or those weighing less than 35kg.

Reason for requested change

Following the domperidone evidence review presented at APC in December 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) published new advice on the use of domperidone in [Drug Safety Update for December 2019](#).²

The MHRA Drug Safety Update states that 'Domperidone is no longer licensed for use in children younger than 12 years or those weighing less than 35kg. Results from a placebo-controlled study in children younger than 12 years with acute gastroenteritis did not show any difference in efficacy at relieving nausea and vomiting compared with placebo.'

It advises healthcare professionals:

- domperidone is now authorised for the relief of symptoms of nausea and vomiting only in adults and adolescents 12 years of age or older and weighing 35 kg or more
- to consider alternative treatments to domperidone in children younger than 12 years of age who need relief of symptoms of nausea and vomiting

In addition **the MHRA recognises that 'Domperidone is also used outside of its authorised indications in children in the UK** for gastrokinetic effects in conditions other than nausea and vomiting. If a specialist physician considers, based on their professional judgement and available evidence of the medical condition, that domperidone use in any condition is justified in a child younger than 12 years, the patient or parent/caregiver should be fully informed of the potential benefits and risks of the different options (please see previous guidance on off-label use in [Drug Safety Update, April 2009](#)).'³

Key Considerations

Cost implications to the local health economy

NHS price for generic preparations (Feb 2020):⁴

30 x10mg tablets = £0.88

200ml 1mg/ml sugar-free oral suspension = £24.85

As per evidence review: Current annual spend (Sep 18 – Aug 19):

	Tablets items	Tablets cost	Liquid items	Liquid cost	Suppository items	Suppository cost
Crawley CCG	861	£1,455	74	£2,957		
East Surrey CCG	899	£1,821	167	£9,201		
Guildford & Waverley CCG	839	£1,416	88	£7,335		
Horsham & Mid Sussex CCG	1079	£2,318	222	£10,817	2	£115
North West Surrey CCG	1250	£2,370	150	£4,728		
Surrey Downs CCG	1066	£2,227	165	£7,534		
Surrey Heath CCG	420	£926	65	£3,325		
TOTAL	6414	£12,537	931	£45,902	2	£115

Total annual spend: £58,555

Availability of PAS and details (if appropriate): [Not applicable.](#)

Availability of homecare service (if appropriate): [Not applicable.](#)

Impact to current prescriber or medication initiator

Delays in the transfer of prescribing of domperidone for off-label indications in children under 12 years or under 35kg to specialists could mean primary care prescribers continue to take clinical responsibility despite the change in licensing of domperidone.

Impact to proposed prescriber or medication initiator
<ul style="list-style-type: none"> • Potential increase in the prescribing of alternative medication and formulations and their associated cost implications • Increase in appointments/visits to hospital
Impact to patients
If primary care prescribers are not prepared to continue prescribing, this has implications on patients including difficulties in obtaining supplies which may result in additional hospital visits.
Additional comments
<ul style="list-style-type: none"> • There may be additional costs for the CCG in terms of hospital appointments.
Identified lead for development of necessary documents e.g. shared care agreement
Kwame Oduro, Primary Care Pharmacist, East Surrey CCG
Estimated date of preparation: April 2020

References:

1. Electronic Medicines Compendium. Motilium 10mg film coated tablets SPC. Available at: <https://www.medicines.org.uk/emc/product/4177> (Last Accessed 10/02/2020)
2. Medicines and Healthcare Products Regulatory Agency. Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolescents. December 2019. Available at: <https://www.gov.uk/drug-safety-update/domperidone-for-nausea-and-vomiting-lack-of-efficacy-in-children-reminder-of-contraindications-in-adults-and-adolescents#reminder-on-the-safe-use-of-domperidone-in-accordance-with-the-product-information> (Last Accessed 10/02/2020).
3. Medicines and Healthcare Products Regulatory Agency. Off-label or unlicensed use of medicines: prescribers' responsibilities. December 2014. Available at: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities> (Last Accessed 10/02/2020)
4. NHS Business Services Authority. Drug Tariff Online. February 2020. Available at: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff> (Last Accessed 10/02/2020)

Prepared by:

Kwame Oduro, Primary Care Pharmacist, East Surrey CCG

Declaration of Interest:

None

Date: 10/02/2020

Reviewed by:

Tejinder Bahra, Lead Commissioning Pharmacist, Surrey Downs CCG

Declaration of Interest:

None

Date: 11.2.20

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
<i>v.1</i>	<i>12/02/2020</i>	<i>Kwame Oduro</i>	<i>Draft</i>	<i>Out for consultation</i>
<i>v.2</i>	<i>26/02/2020</i>	<i>Kwame Oduro</i>	<i>Final</i>	<i>Comments from consultation added</i>

FINAL