

**From the Chief Medical Officer  
Dr Michael McBride**



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

**HSS(MD) 16/2020**

**FOR ACTION**

Chief Executives of HSC Trusts  
GP Medical Advisers, Health and Social Care Board All  
General Practitioners and GP Locums (for onward  
distribution to practice staff)  
Director of Integrated Care, Health and Social Care Board  
Chief Executive RQIA (for onward transmission to all  
independent providers including independent  
hospitals)  
Assistant Director of Pharmacy and Medicines  
Management, Health and Social Care Board (for onward  
distribution to Community Pharmacies)

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Stormont Estate  
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Our Ref: HSS(MD) 16/2020

Date: 26 March 2020

**PLEASE SEE ATTACHED FULL CIRCULATION LIST**

Dear Colleague

**DIAMORPHINE HYDROCHLORIDE POWDER FOR RECONSTITUTION AND  
INJECTION 5MG AND 10MG AMPOULES – UPDATED SUPPLY DISRUPTION  
ALERT**

This letter is an update to our previous letter HSS(MD) 10/2020 issued on 28 February 2020. This update asks healthcare professionals to make permanent the recommended actions originally communicated on 28 February 2020.

The UK has been experiencing intermittent supply issues of diamorphine 5mg and 10mg injection since May 2018. There are two suppliers of diamorphine hydrochloride 5mg and 10mg in the UK, Wockhardt and Accord. Accord are currently out of stock of both 5mg and 10mg strengths, with an estimated re-supply date of Summer 2020. Wockhardt are out of both 5mg and 10mg strengths with limited supplies expected to be available week commencing 6 April 2020. The indication from both suppliers of diamorphine 5mg and 10mg strengths is that the supply will remain unpredictable for the foreseeable future. Diamorphine hydrochloride 30mg, 100mg and 500mg are available but manufacturers are unable to support an increase in demand on these strengths.

On 28 February 2020 both primary and secondary care were asked to switch use of diamorphine to morphine until the Wockhardt re-supply in early April. As both

suppliers of diamorphine have indicated further disruption to supply is likely for the foreseeable future, the Department of Health and Social Care have been engaging with national clinical leads and suppliers of morphine and diamorphine to plan for a UK wide decrease in usage of diamorphine to morphine. The small quantities of diamorphine 5mg and 10mg, which may still be available in the UK over the coming months, should be reserved for patients who cannot be treated with alternatives.

Diamorphine is used extensively in secondary care mainly for the treatment of severe pain in obstetrics, surgery and in palliative care. The use in primary care is mainly for palliative care patients. There is some use of diamorphine for substance misuse related indications, but this is generally at much higher doses and therefore it is unlikely that a shortage of the 5mg and 10mg vials will have an impact on these patients.

Morphine sulphate is deemed to be an appropriate alternative to diamorphine hydrochloride for most patients. Morphine and diamorphine are not equipotent, and care should be taken when switching patients or amending guidelines. A clinical guidance document has been developed by UKMi to support local management plans;

<https://www.sps.nhs.uk/articles/shortage-of-diamorphine-5-and-10mg/>

Sufficient supplies of morphine sulfate 10mg/ml injection are available from Ethypharm (Martindale) and Hameln to support to ensure continuity of supply. The Hameln presentation is preservative free.

## **Actions for healthcare professionals**

### **Primary Care**

**The actions below were communicated on 28 February 2020 HSS(MD) 10/2020, there is no change to these actions. Primary care providers as outlined below should ensure that the steps taken are now made permanent.**

All healthcare professionals in primary care who prescribe, dispense or administer diamorphine hydrochloride injection 5mg and 10mg should:

- Identify a local lead within their organisation to manage the delivery of actions as advised in this document where possible;
- Review and update guidelines and protocols, **permanently** moving to morphine sulphate injection as opioid of choice, where clinically appropriate, in place of diamorphine 5mg and 10mg for the duration of this supply disruption;
- Identify and deliver required education and training to General Practice and community nursing teams to support the switch over to morphine;
- Ensure no new patients are started on diamorphine hydrochloride 5mg or 10mg injection;

- Review patients currently receiving diamorphine 5mg or 10mg injection and manage the switch to an alternative opioid;
- Not switch patients to higher strengths of diamorphine injection as there is insufficient stock to support increased use;
  - Consider morphine 10mg/ml injection as the first line opioid, supplies of other alternative opioid agents are limited and should be prescribed for patients where morphine is not clinically appropriate while stocks remain; and
  - Place orders for morphine sulfate 10mg/1ml solution for injection ampoules (Ethypharm and Hameln) from major wholesalers.

## Secondary Care

**The actions below were communicated on 28 February 2020 HSS(MD) 10/2020, there is no change to these actions. Secondary care providers as outlined below should ensure that the steps taken are now made permanent.**

All healthcare professionals in secondary care who prescribe, dispense or administer diamorphine should work with their Head of Pharmacy and Medicines Management to:

- Identify a local lead within their organisation to manage the delivery of actions as advised in this document and appropriate cascade of information to clinical areas and teams impacted;
- Review and update guidelines and protocols, **permanently** moving to morphine sulphate 10mg/1ml injection as opioid of choice in place of diamorphine 5mg and 10mg for the duration of this supply disruption, clearly identifying groups of patients or indications for whom any available diamorphine should be reserved;
- Identify and deliver required education and training to clinical teams to support the move over to morphine;
- Ensure no new patients are started on diamorphine hydrochloride 5mg or 10mg injection;
- Manage the switch over to morphine for patients currently on diamorphine where this is deemed safe and clinically appropriate;
- Centralise all diamorphine at the Trust pharmacy and reserve remaining stock for use in patients who cannot be treated with alternatives;
- Only order diamorphine hydrochloride 5mg and 10mg injection to meet individual patient demand once local stock holding has been used, while stocks remain;

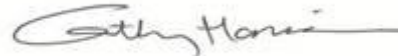
- Not change prescribing practice to alternative opioids, other than morphine 10mg/1ml, unless the regional pharmacy procurement specialist has confirmed sufficient stock is available to support an uplift; and
- Order morphine sulfate 10mg/1ml solution for injection ampoules from major wholesalers for Ethypharm (Martindale) and direct for Hameln product.

Please refer to the attached DHSC Supply Disruption Alert for further information.

This alert can also be accessed at:

<https://www.cas.mhra.gov.uk/ViewAndAcknowledgment/viewAlert.aspx?AlertID=103005>

Yours sincerely

**DR MICHAEL McBRIDE**  
Chief Medical Officer

**MRS CATHY HARRISON**  
Chief Pharmaceutical Officer

### **Circulation List**

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)

Assistant Director Public Health (Health Protection), Public Health Agency

Director of Nursing, Public Health Agency

Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board (*for onward distribution to Community Pharmacies*)

Directors of Pharmacy HSC Trusts

Director of Social Care and Children, HSCB

Family Practitioner Service Leads, Health and Social Care Board (*for cascade to GP Out of Hours services*)

Medical Directors, HSC Trusts (*for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads*)

Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses, and Midwives*)

Directors of Children's Services, HSC Trusts

RQIA (*for onward transmission to all independent providers including independent hospitals*)

Medicines Management Pharmacists, HSC Board (*for cascade to prescribing advisers*)

Regional Medicines Information Service, Belfast HSC Trust

Regional Pharmaceutical Procurement Service, Northern HSC Trust

Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB

Professor Sonja McIlfatrick, Head of School of Nursing, University of Ulster

Caroline Lee, CEC

Donna Gallagher, Open University

Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU

Professor Carmel Hughes, Head of School, School of Pharmacy, QUB  
Professor Colin Adair, Director of the NI Centre for Pharmacy Learning and  
Development, QUB  
Joe Brogan, Assistant Director of Integrated Care, HSCB  
Michael Donaldson (*for distribution to all General Dental Practitioners!*)

This letter is available on the Department of Health website at  
[https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-  
advice/hssmd-letters-and-urgent-communications](https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications)



9 February 2018

Dear Healthcare Professional

**Esmya (ulipristal acetate) for uterine fibroids: monitor liver function in current and recent users; do not initiate treatment in new users or those between treatment courses**

I am writing to inform you of new temporary safety measures which have been introduced for Esmya following reports of serious liver injury in women using the medicine for uterine fibroids.

**Summary**

Five reports of serious liver injury, including four cases of hepatic failure needing liver transplantation, have been reported worldwide in women using Esmya for uterine fibroids. The following temporary safety measures have been introduced while an EU-wide review of the evidence is ongoing:

- Do not initiate new treatment courses of Esmya, including in women who have completed one or more treatment courses previously
- Perform liver function tests at least once a month in all women currently taking Esmya. Stop Esmya treatment in any woman who develops transaminase levels more than 2 times the upper limit of normal, closely monitor and refer for specialist hepatology evaluation as clinically indicated. Liver function tests should be repeated in all women 2 to 4 weeks after stopping treatment.
- Check transaminase levels immediately in current or recent users of Esmya who present with signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice). If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist hepatology evaluation as clinically indicated.
- Advise women using Esmya on the signs and symptoms of liver injury.

We will provide further information as soon as this review is completed.

The emergency contraceptive ellaOne also contains ulipristal acetate (single-dose, 30mg). No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.



## Supply Disruption Alert - Update

SDA/2020/003(U)

Issued: 25 March 2020

Diamorphine Hydrochloride powder for reconstitution and injection 5mg & 10mg ampoules – Supply Disruption Alert Update

### Summary

This update asks healthcare professionals to make permanent the recommended actions originally communicated on 26 February 2020 (SDA/2020/003).

- There are two suppliers of diamorphine hydrochloride 5mg and 10mg in the UK, Wockhardt and Accord.
- Accord are out of stock of both 5mg and 10mg strengths, with a re-supply date of Summer 2020.
- Wockhardt are out of both 5mg and 10mg strengths with limited supplies expected to be available w/c 6<sup>th</sup> April 2020.
- The indication from both suppliers of diamorphine 5mg and 10mg strengths is that the supply will remain unpredictable for the foreseeable future.
- Diamorphine hydrochloride 30mg, 100mg, 500mg are available but manufacturers are unable to support an increase in demand on these strengths.
- Morphine sulfate solution for injection 10mg/ml has been identified by clinical experts as the most likely first-line alternative and both primary and secondary care were advised to temporarily switch to morphine, where clinically appropriate, on 25<sup>th</sup> February 2020 (SDA/2020/003). Given the continuing unpredictability of supply of diamorphine both primary and secondary care should now make this change permanent.
- Morphine and diamorphine are not equipotent, and care should be taken when switching patients or amending guidelines, the UKMi memo (link in problem/background section below) gives further information.
- Sufficient supplies of morphine sulfate 10mg/ml injection are available from Ethypharm and Hameln to ensure continuity of supply. The Hameln presentation is preservative free.

### Action

#### PRIMARY CARE

The actions below were communicated on 25<sup>th</sup> February 2020 (SDA/2020/003), there is no change to these actions. Primary care providers as outlined below should ensure that the steps taken are now made permanent.

All healthcare professionals in primary care who prescribe, dispense or administer diamorphine hydrochloride injection 5mg and 10mg should:

- identify a local lead within their organisation to manage the delivery of actions as advised in this document where possible;
- review and update guidelines and protocols, moving to morphine sulphate injection as opioid of choice, where clinically appropriate, in place of diamorphine 5mg and 10mg;

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- identify and deliver required education and training to General Practice and community nursing teams to support the switch over to morphine;
- ensure no new patients are started on diamorphine hydrochloride 5mg or 10mg injection;
- review patients currently receiving diamorphine 5mg or 10mg injection and manage the switch to an alternative opioid;
- not switch patients to higher strengths of diamorphine injection as there is insufficient stock to support increased use;
- consider morphine 10mg/ml injection as the first line opioid as supplies of alternative opioid agents are limited and these should be prescribed for patients where morphine is not clinically appropriate; and
- place orders for morphine sulfate 10mg/1ml solution for injection ampoules (Ethypharm (Martindale) and Hameln) from major wholesalers.

## SECONDARY CARE

The actions below were communicated on 25<sup>th</sup> February 2020 (SDA/2020/003), there is no change to these actions. Secondary care providers as outlined below should ensure that the steps taken are now made permanent.

All healthcare professionals in secondary care, including hospices, who prescribe, dispense or administer diamorphine should work with their local Medication Safety Officer (MSO) to:

- identify a local lead within their organisation to manage the delivery of actions as advised in this document and appropriate cascade of information to clinical areas and teams impacted;
- review and update guidelines and protocols, permanently moving to morphine sulphate 10mg/1ml injection as opioid of choice in place of diamorphine 5mg and 10mg, clearly identifying groups of patients or indications for whom any available diamorphine should be reserved;
- identify and deliver required education and training to clinical teams to support the move over to morphine;
- ensure no new patients are started on diamorphine hydrochloride 5mg or 10mg injection;
- manage the switch over to morphine for patients currently on diamorphine where this is deemed safe and clinically appropriate;
- centralise all diamorphine at the Trust or Health Board pharmacy and reserve remaining stock for use in patients who cannot be treated with alternatives;
- only order diamorphine hydrochloride 5mg and 10mg injection to meet individual patient demand once local stock holding has been used, while stocks remain;
- not change prescribing practice to alternative opioids, other than morphine 10mg/1ml, unless the regional pharmacy procurement specialist has confirmed sufficient stock is available to support an uplift; and
- order morphine sulfate 10mg/1ml solution for injection ampoules from major wholesalers for Ethypharm (Martindale) and direct for Hameln product.

### Deadlines for actions

Actions initiated: on receipt of this alert  
Actions completed: 06 April 2020

Note: no response is required to this alert via the Central Alerting System.

## Product details

Diamorphine hydrochloride powder for reconstitution and injection 5mg and 10mg ampoules (Wockhardt and Accord).

## Problem / background

Diamorphine is used extensively in secondary care mainly for the treatment of severe pain in obstetrics, surgery and in palliative care. The use in primary care is mainly for palliative care patients. There is some



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use of diamorphine for substance misuses related indications, but this is generally at much higher doses and therefore it is unlikely that a shortage of the 5mg and 10mg vials will have an impact on these patients.

The UK has been experiencing intermittent supply issues of diamorphine 5mg and 10mg injection since May 2018. On 25<sup>th</sup> February both primary and secondary care were asked to switch use of diamorphine to morphine until the Wockhardt re-supply in early April. Both suppliers of diamorphine have indicated further disruption to supply is likely for the foreseeable future. In light of this NHS England and Improvement and the Department of Health and Social Care have been engaging with national clinical leads and suppliers of morphine and diamorphine to plan for a national decrease in usage of diamorphine to morphine, where the supply chain is more robust. The small quantities of diamorphine 5mg and 10mg, which may still be available in the UK over the coming months, should be reserved for patients who cannot be treated with alternatives.

Morphine sulphate is deemed to be an appropriate alternative to diamorphine hydrochloride for most patients. A clinical guidance document has been developed by UKMi to support local management plans <https://www.sps.nhs.uk/articles/shortage-of-diamorphine-5-and-10mg/>.

## Distribution

### Trusts (NHS boards in Scotland and Wales)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- District nurses
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Immunologists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Intensive care, directors of
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Palliative care teams
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Theatre managers
- Theatre nurses

### NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists

### General Practice

For onward distribution to all relevant staff including:

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- General practitioners
  - General practice managers
  - General practice nurses
- Independent distribution**

**Establishments registered with the Care Quality Commission (CQC) (England only)**

- Care homes providing nursing care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

## Enquiries

### England

Enquiries from NHS Trusts in England should in the first instance be directed to your trust pharmacy team who will escalate issues to the Regional Pharmacy Procurement Specialist and national teams if required.

REGION	Full Name	Email
East Midlands	Andi Swain	<a href="mailto:andi.swain@nhs.net">andi.swain@nhs.net</a>
East of England	James Kent	<a href="mailto:james.kent@southend.nhs.uk">james.kent@southend.nhs.uk</a>
London	Jackie Eastwood	<a href="mailto:jacqueline.eastwood@lpp.nhs.uk">jacqueline.eastwood@lpp.nhs.uk</a>
North East	David Cook	<a href="mailto:David.Cook@nth.nhs.uk">David.Cook@nth.nhs.uk</a>
North West	Glenn Harley	<a href="mailto:Glenn.Harley@liverpoolft.nhs.uk">Glenn.Harley@liverpoolft.nhs.uk</a>
South Central	Alison Ashman	<a href="mailto:Alison.Ashman@berkshire.nhs.uk">Alison.Ashman@berkshire.nhs.uk</a>
South East Coast	Richard Bateman	<a href="mailto:richard.bateman2@nhs.net">richard.bateman2@nhs.net</a>
South West	Danny Palmer	<a href="mailto:Danny.Palmer@UHBristol.nhs.uk">Danny.Palmer@UHBristol.nhs.uk</a>
West Midlands	Sumara Parvez	<a href="mailto:Sumara.parvez@swift.nhs.uk">Sumara.parvez@swift.nhs.uk</a>
Yorkshire & Humber	David Allwood	<a href="mailto:davidallwood@nhs.net">davidallwood@nhs.net</a>

### Scotland

[NSS.NHSSMedicineShortages@nhs.net](mailto:NSS.NHSSMedicineShortages@nhs.net)

### Wales

[MedicinesShortages@gov.wales](mailto:MedicinesShortages@gov.wales)

### Northern Ireland

[Noel.dunn@northerntrust.hscni.net](mailto:Noel.dunn@northerntrust.hscni.net)

All other organisations should send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number SDA/2020/003(U)

Email: [supplyresiliencemd@dhsc.gov.uk](mailto:supplyresiliencemd@dhsc.gov.uk)