



Llywodraeth Cymru
Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

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| Distribution: | As Annex 1 |
| From: | Andrew Evans, Chief Pharmaceutical Officer |
| Date: | 11 April 2019 |
| Reference: | CPhO/MedsLet/2019/01 |
| Category: | Level 3 - High impact |
| Title: | Disruption to supply of Levomepromazine 25mg/ml solution for injection. |
| For Action by: | <ul style="list-style-type: none">• All General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'. - Action as below and attached Clinical Memo.• Dispensing General Practitioners – please ensure this message is seen by all working in your dispensary and retain a copy in your 'locum information pack'. Action as below and attached Clinical Memo.• Community Pharmacists - Action as below and attached Clinical Memo.• Hospital Chief Pharmacists - Action as below and attached Clinical Memo.• Medical Directors of Health Boards - disseminate to relevant clinicians in secondary care setting. |
| Timeframe: | Action within 24 hrs |



BUDDSODDWYR | INVESTORS
MEWN POBL | IN PEOPLE

Parc Cathays • Cathays Park
Caerdydd • Cardiff
CF10 3NQ

Medicines.Shortages@gov.wales
Gwefan • website:
<https://gov.wales/topics/health/professionals/pharmaceutical/?lang=en>

For Information: See Annex 1 – Distribution List

Key Recipients:

Chief Executives of Health Boards
Nurse Directors Health Boards
Directors of Public Health
Health Board and NHS Trust Chief Pharmacists
Health Board Prescribing Advisers
Chief Executives of NHS Trusts
Principal Pharmacist Welsh Quality Control
Principal Pharmacist Continuing Care Services
Principal Pharmacist Welsh Medicines Information Centre
CIW
NHS Direct

What is this about:

Medicine shortage affecting supply of Levomepromazine 25mg/ml solution for injection.

Levomepromazine is a phenothiazine antipsychotic. It possesses anti-emetic, antihistamine and anti-adrenaline activity and exhibits a strong sedative effect. It is licensed for the management of pain and accompanying restlessness or distress in the terminally ill patient. In the palliative care setting, it is widely used for terminal agitation and as a second line anti-emetic agent.

Issue & Action to be taken:

Action

Levomepromazine is an essential medication in the inpatient and community setting. Patients on this drug may already have been treated with first line parenteral agents such as haloperidol or midazolam, alone or in combination, for terminal agitation; or cyclizine, haloperidol, and metoclopramide for nausea and vomiting, where the multi-receptor blockade of levomepromazine makes it a useful choice when symptoms are thought to be due to more than one cause.

Therefore, should stock of levomepromazine run out, management options will need to be determined on a case by case basis, if necessary in consultation with the specialist palliative care teams.

Management Plan – GPs, Palliative Care Networks and Community Pharmacies to review and action immediately

During the period of shortage, new patients should only be started on levomepromazine if other treatment options have been exhausted. This is to try to avoid disrupting existing treatment regimens where possible whilst acknowledging that for some new patients levomepromazine may be the only option available.

Community pharmacies who require stock for existing patients should order Wockhardt stock from Alliance.

Community pharmacies having difficulty obtaining stock should contact their health board chief pharmacist as they have been asked to support primary care and hospices where possible, if they have stock that can be made available to allow the continuation of treatment in existing patients.

Some specialist importers have identified stock they can bring into the UK. Lead times vary between 7-21 days. If community pharmacies are considering ordering unlicensed imports, the community pharmacist will need to inform the prescribing doctor the product being supplied to the patients is an unlicensed product. Please consider placing orders now for 1-2 weeks of stock based on forecasted demand. We are currently aware that Clinigen, Waymade, Alium and Mawdsleys have sourced unlicensed supplies from abroad.

Community pharmacies unable to obtain levomepromazine injection should liaise with the prescriber to discuss using an alternative product as outlined in the attached Clinical Memo.

Reasons for shortage

Sanofi, have experienced a component delay, this has had to be re-ordered and they will initiate production w/c 15/04/19. Sanofi will be out of stock from the end of this week (12th April 2019) until the end of April. The only other UK supplier, Wockhardt, anticipate they will be out of stock this week due to the unexpected increase in demand; their next delivery has been delayed and further stock will not be available until the end of April.

All Hospital Chief Pharmacists, Health Board Prescribing Advisers and Medical Directors of Health Boards to ensure all relevant prescribers and dispensers in secondary care settings receive this medicines shortage letter and attached Clinical Memo.

Full details of the medicine supply disruption are included in the attached PDF file.

Please forward to listed recipients.

This information is also published on:

<https://gov.wales/topics/health/professionals/pharmaceutical/?lang=en>

Yours sincerely



Andrew Evans

Chief Pharmaceutical Officer/Prif Swyddog Fferyllo
Welsh Government/Llywodraeth Cymru

DISTRIBUTION LIST

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Medical Directors of Health Boards
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NHS Wales Shared Services Partnership to forward to:

General Practitioners
Dispensing General Practitioners
Community Pharmacists
Independent / Private clinics and hospitals and hospices throughout
Wales

Welsh Government:

Chief Medical Officer
Chief Nursing Officer
Chief Dental Officer
Chief Optometric Officer
Chief Scientific Officer

Chief Therapies Officer

Director General Health and Social Services Group

Emergency Planning Adviser



Llywodraeth Cymru
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CLINICAL MEMO

Levomepromazine 25mg/ml solution for injection.

Description of product affected

Levomepromazine is a phenothiazine antipsychotic which acts as an antagonist at the D₂, 5HT_{2A}, α_1 and α_2 -adrenergic, H₁ and muscarinic receptor sites.¹ It possesses anti-emetic, antihistamine and anti-adrenaline activity and exhibits a strong sedative effect. It is licensed for the management of pain and accompanying restlessness or distress in the terminally ill patient.^{2,3} In the palliative care setting, it is widely used for terminal agitation and as a second line anti-emetic agent.¹

Background

Sanofi, one of the manufacturers of levomepromazine will be out of stock from the end of this week (12th April 2019) until the end of April. The only other UK supplier, Wockhardt, anticipate they will be out of stock this week due to the unexpected increase in demand; their next delivery has been delayed and further stock will not be available until the end of April.

Alternative agents and management options

Levomepromazine is an essential medication in the inpatient and community setting. Patients on this drug may already have been treated with first line parenteral agents such as haloperidol or midazolam, alone or in combination, for terminal agitation¹; or cyclizine, haloperidol, and metoclopramide for nausea and vomiting¹, where the multi-receptor blockade of levomepromazine makes it a useful choice when symptoms are thought to be due to more than one cause.⁴ Therefore, should stock of levomepromazine run out, management options will need to be determined on a case by case basis, in consultation with the specialist palliative care teams.

References

1. Palliative Care Formulary Sixth Edition, 2017
2. Wockhardt UK Ltd. Levomepromazine Hydrochloride 25mg/ml Solution for Injection. SPC, date of revision of text, 26/04/2017: <https://www.medicines.org.uk/emc/product/3014>
3. SANOFI. Nozinan 25mg/ml Solution for Injection/Infusion. SPC, date of revision of text, 30 August 2017: <https://www.medicines.org.uk/emc/product/1428/smpc>

4. London Clinical Networks. Improving the quality of care in the last days of life. A practical guide to getting the medications right (July 2016):
<http://www.londonscn.nhs.uk/publication/improving-the-quality-of-care-in-the-last-days-of-life/>

Acknowledgements

- Dr Shaheen Khan, Consultant in palliative medicine, lead clinician for Guy's and St Thomas' NHS Foundation Trust community palliative care team
- Dr Bill Crawley (GPSI palliative medicine), Pilgrims Hospices, Canterbury
- Margaret Gibbs, Lead Palliative Care Clinical Pharmacist, Ashton's Hospital Pharmacy Services

Original document prepared by:

Yuet Wan, London and South East Regional Medicines Information, Guy's and St Thomas' NHS Foundation Trust, 11 April 2019.

Reviewed by clinical experts in Wales, on behalf of Welsh Government and NHS Wales.

For all correspondence please contact:

Pharmacyand.prescribingbranch@gov.wales

Disclaimer: This memo can be adapted for local use. The content does not reflect national guidance. Some of this memo is based on **clinical opinion** from practitioners. Users should bear this in mind in deciding whether to base their policy on this document. Individual local health boards and NHS trusts should ensure that procedures for unlicensed medicines are followed where a foreign import drug is required in the interim. Any decision to prescribe off-label must take into account the relevant GMC guidance and local governance procedures for unlicensed medicines. Prescribers are advised to pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label.