



Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

MEDICINE / DRUG IN SHORT SUPPLY: PROVERA® (MEDROXYPROGESTERONE ACETATE) 100MG TABLETS

Priority: Level 2
Valid until: 8 November 2019

Issue

1. This Medicine Supply Alert Notice provides NHS Boards, Community Pharmacies and Healthcare Professionals on the current supply issues affecting **Provera® (medroxyprogesterone acetate) 100mg tablets.**

Details

2. This supply issue affects Pfizer, the sole supplier of Provera® tablets. Pfizer has informed the Department of Health and Social Care (DHSC) that due to manufacturing delays, they are out of stock of the 100mg tablets until week ending 8 November 2019. Provera® 200mg and 400mg tablets remain available.

Action required

3. For patients who do not have sufficient supplies of Provera® 100mg tablets for the duration of the expected out of stock period, **clinicians should consider prescribing an unlicensed preparation** of medroxyprogesterone tablets.

4. The DHSC has contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad.

5. Clinicians will need to work with local community pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times.

23 September 2019

Addressees:

For action

NHS Directors of Pharmacy
NHS Medical Directors
Pharmacy Primary Care Leads
Medicines Information
Pharmacists
Community Pharmacy Scotland
NHS National Procurement
Scottish Prescribing Advisor
Network

For information

Director Practitioner Services,
NHS NSS
NHS Scotland Chief Executives
NHS Directors of Finance

General Enquiries to:

Margaret Syme or Alison Strath
Pharmacy & Medicines Division

Email: PharmacyTeam@gov.scot

www.gov.scot

6. Any decision to prescribe unlicensed medicines must consider the relevant guidance and Health Board local governance procedures.

Action

7. Health Board Medical Directors and Directors of Pharmacy are asked to cascade this Medicines Supply Alert Notice to general practices, community pharmacies, and other relevant professionals in their Health Board area.

8. Healthcare professionals are asked to note the content and actions outlined in this circular and Annexes.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Rose Marie Parr". The signature is written in a cursive, flowing style.

Rose Marie Parr
Chief Pharmaceutical Officer/
Deputy Director Pharmacy & Medicines Division

MEDICINES SUPPLY ALERT NOTICE: PROVERA® (MEDROXYPROGESTERONE ACETATE) 100MG TABLETS

20 September 2019

Dear Colleagues,

Please be aware that there is an important drug supply issue affecting **Provera® (medroxyprogesterone acetate) 100mg tablets**

- Pfizer, the sole supplier of Provera® tablets, has informed the Department of Health and Social Care (DHSC) that due to manufacturing delays, they are out of stock of the 100mg tablets until week ending 8th November 2019.
- Provera® 200mg and 400mg tablets remain available.

Action required by recipients:

- **Clinicians should consider prescribing an unlicensed preparation of medroxyprogesterone tablets for patients who do not have sufficient supplies of Provera® 100mg tablets for the duration of the expected out of stock period.**
 - The DHSC has contacted specialist importer companies who have advised that unlicensed imports can be sourced from abroad.
 - Importers who have currently confirmed they can source these lines, include:

Medroxyprogesterone 100mg tablets	Mawdsley's
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- Clinicians will need to work with local community pharmacies to understand more about the specific unlicensed products that can be sourced and associated lead times.
 - Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board local governance procedures. Please see the links below for further information:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products_specials.pdf
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/toolkit/specials-professional-guidance.pdf>
- To minimise the disruption this may cause locally in terms of patients seeking GP appointments, GP practices may want to consider identifying patients who may be impacted by this shortage and to manage these patients by prescribing unlicensed supplies where appropriate.
 - For patients **in whom unlicensed supplies are not considered appropriate** a discussion with or referral to secondary care cancer specialists will be required for consideration of alternative options, as included in the UKMI memo below:
<https://www.sps.nhs.uk/articles/shortage-of-provera-medroxyprogesterone-acetate-100mg-tablets/>

Medicines Shortages Response Group (Scotland) priority definitions

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where <u>immediately available measures are expected to be sufficient</u> and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. <ul style="list-style-type: none"> Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where <u>alternatives in the same therapeutic class are available but which may require some management</u> such as switching to those alternatives, which may include unlicensed medicines. Level two shortages also include level one shortages that continue for more than a month.	Business as usual. Response not likely to require a change in the class of medicine. <ul style="list-style-type: none"> Alternative strength/formulation available but clinical advice is required to help manage the switch. Alternative medicine in the same therapeutic class. Unlicensed alternatives may be available.
Level three (high impact)	Supply problems where there are <u>limited or no alternatives in the same therapeutic class and which require significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient groups considered as vulnerable</u> , such as neonates, pediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the therapeutic class of medicine. <ul style="list-style-type: none"> Alternative therapeutic class of medicine available. The use of a 'serious shortage protocol'. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a 'Supply Disruption Alert' to the NHS via the Central Alerting System (CAS).
Level four (critical impact)	Supply problems where there is <u>no viable therapeutic alternative</u> and were responses may also require support from the wider NHS and outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. <ul style="list-style-type: none"> Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required.

NHS Circular:
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