



Llywodraeth Cymru
Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

Distribution:	As Annex 1
From:	Andrew Evans, Chief Pharmaceutical Officer
Date:	26 September 2019
Reference:	CPhO/MedsLet/2019/15
Category:	Level 3 - High impact
Title:	Disruption to supply of Medroxyprogesterone Acetate (Provera®) 100mg Tablets
For Action by:	<ul style="list-style-type: none">• All General Practitioners - retain a copy in your 'locum information pack'. Action as below.• 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.• Community Pharmacists - Action as below.• Hospital Chief Pharmacists - Action as below.• Medical Directors of Health Boards - disseminate to relevant clinicians in secondary care setting – Action as below.
Timeframe:	Action within 24 hrs
For Information:	See Annex 1 – Distribution List
Key Recipients:	<p>Chief Executives of Health Boards</p> <p>Nurse Directors Health Boards</p>

Directors of Public Health
Health Board and NHS Trust Chief Pharmacists
Health Board Prescribing Advisers
Chief Executives of NHS Trusts
Director Welsh Medicines Information Centre
NHS Direct Wales

What is this about:

Disruption to the supply of Medroxyprogesterone Acetate (Provera®) 100mg Tablets.

Description of product affected:

Medroxyprogesterone Acetate (Provera®) 100mg Tablets.

Provera® 200mg and 400mg tablets remain available but are unable to bridge the gap without going out of stock.

Indication:

Provera is licensed for the treatment of certain hormone dependant neoplasms, such as:¹

1. Endometrial carcinoma.
2. Renal cell carcinoma.
3. Carcinoma of breast in post-menopausal women.

It has also been used off label for the treatment of anorexia and cachexia in cancer, and treatment induced hot flushes in both women and men.²⁻⁴

Issue & Action to be taken:

ISSUE

Disruption to the supply of Medroxyprogesterone Acetate (Provera®) 100mg Tablets is expected until week ending 8 November 2019.

ACTION:

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 as soon as possible.

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
--------------------------------------	------------

Clinicians will need to work with local pharmacies to understand more about the specific

unlicensed products that can be sourced and associated lead times.

In order for pharmacies to dispense an unlicensed drug, WP10 prescriptions must indicate that a special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: "special order".

For patients **in whom unlicensed supplies are not considered appropriate** a referral to secondary care cancer specialists will be required for consideration of alternative options, as included in the UKMI guidance memo below:

<https://www.sps.nhs.uk/articles/shortage-of-provera-medroxyprogesterone-acetate-100mg-tablets/>

GUIDANCE:

When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

Use of unlicensed products should be in line with agreed local policies and guidance.

Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and local governance procedures. Please see link to GMC guidance:

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>

Guidance on supplying specials can be found at:

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>

REFERENCES

1. Pfizer Limited. Provera Tablets 100 mg. SPC; date of revision of the text, 10/2016: <https://www.medicines.org.uk/emc/product/6276/smpc>
2. Palliative Care Formulary, 6th ed, 2017: Progestogens (pg 582)
3. Cancer Research UK. Medroxyprogesterone acetate (Provera), accessed online 28 August 2019: <https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/cancer-drugs/drugs/medroxyprogesterone>
4. BNF, accessed online 28 August 2019: <https://bnf.nice.org.uk/drug/medroxyprogesterone-acetate.html>

QUERIES

For all correspondence please contact:

Medicinesshortages@gov.wales

Please forward to listed recipients.

Yours sincerely



Andrew Evans

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

DISTRIBUTION LIST

Send to:

Chief Executives of Health Boards
Medical Directors of Health Boards
Health Board Chief Pharmacists
Hospital Chief Pharmacists
Chief Executives of NHS Trusts
Director of Welsh Medicines Information Centre
NHS Wales Procurement
NHS Direct

NHS Wales Shared Services Partnership to forward to:

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

Welsh Government:

Chief Medical Officer
Chief Nursing Officer
Chief Dental Officer
Director General Health and Social Services Group
Senior Medical Officer, Maternal and Child Health
Healthcare Quality and Patient Safety
Emergency Planning Adviser
HSSG Comms