



Llywodraeth Cymru
Welsh Government

MEDICINES SHORTAGE ADVISORY GROUP WALES

MEDICINE SHORTAGE

Distribution:	As Annex 1
From:	Andrew Evans, Chief Pharmaceutical Officer
Date:	2 October 2019
Reference:	CPhO/MedsLet/2019/16
Category:	Level 3 - High impact
Title:	Disruption to supply of Fluoxetine 10mg and 30mg and 40mg Capsules
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:	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
Director Welsh Medicines Information Centre
NHS Direct Wales

What is this about:

Disruption to the supply of Fluoxetine 30mg and 40mg Capsules and update on supply disruption to Fluoxetine 10mg Capsules.

Description of product affected:

Fluoxetine 10mg and 30mg and 40mg Capsules.

Issue & Action to be taken:

ISSUE

Please see table below which summarises overall fluoxetine availability:

Fluoxetine strength	Form	MA Holder	Stock Availability
10mg	capsules	Morningside	Unavailable until end of October 2019
10mg	capsules	Advanz	Unavailable until early December 2019
30mg	capsules	Advanz	Unavailable until early November 2019
40mg	capsules	Advanz	Unavailable until early November 2019
10mg	tablets	Endo Ventures Ltd	Available
20mg	capsules	Various suppliers	Available
20mg/5ml	oral solution	Various suppliers	Available

ACTION:

Due to the long-term issues affecting fluoxetine 10mg, 30mg and 40mg capsules, we recommend the following actions be undertaken:

- General Practitioners and prescribers should identify all patients currently prescribed fluoxetine 10mg, 30mg and 40mg capsules.
- Early contact should be made with the patient or patient's parent/carer to determine if the stocks at home will last until early November.

- If the patient has sufficient supplies to last them until early November, then no further action is required. These patients should **not** be issued with a repeat prescription during this period.
- For patients who do not have sufficient supplies for the duration of the expected out of stock period, prescribers should consider the following:

Current prescription	Suggested alternatives:
<u>Fluoxetine 10mg capsules</u>	Fluoxetine 10mg tablets Or Fluoxetine 20mg/5ml oral solution* Or Unlicensed fluoxetine 10mg capsules (see further info below)
<u>Fluoxetine 30mg capsules</u>	Fluoxetine 10mg tablets + fluoxetine 20mg capsules Or Fluoxetine 20mg/5ml oral solution*
<u>Fluoxetine 40mg capsules</u>	Fluoxetine 20mg capsules Or Fluoxetine 20mg/5ml oral solution*

*Please note that the oral solution has the same bioavailability as the capsules/tablets - so can be used to make up the equivalent dose e.g.

10mg = 2.5ml

30mg = 7.5ml

40mg = 10ml

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".

Unlicensed Preparations

DHSC have also 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:

Fluoxetine 10mg capsules	Target Healthcare Ltd
Fluoxetine 10mg tablets	Mawdsley's
	Alium Medical
	Waymade PLC

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



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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
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Director General Health and Social Services Group
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