

Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

MEDICINE / DRUG IN SHORT SUPPLY: FLUOXETINE 10MG, 30MG & 40MG CAPSULES

Priority: Level 2
Valid until: October – December 2019 (detail below)

Issue

1. This Medicine Supply Alert Notice provides NHS Boards, Community Pharmacies and Healthcare Professionals and teams on the current supply issues affecting **fluoxetine 10mg, 30mg and 40mg capsules** due to manufacturing issues.

Details

2. This supply issue affects the medicines as set out in the table below.

Strength	Form	MA holder	Unavailable until
10mg	Capsules	Morningside	End October 2019
10mg	Capsules	Advanz	Early December 2019
30mg	Capsules	Advanz	Early November 2019
40mg	Capsules	Advanz	Early November 2019

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

Management Plan

3. Due to the long-term issues affecting fluoxetine 10mg, 30mg and 40mg capsules, the Department of Health and Social Care recommends the following actions should 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 actions as set out in Annex A.

Action

4. 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.

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

Yours sincerely,



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

MEDICINES SUPPLY ALERT NOTICE: FLUOXETINE 10MG, 30MG & 40MG CAPSULES

20 September 2019

Dear Colleagues,

Please be aware that there is a supply issue affecting fluoxetine 10mg, 30mg and 40mg capsules due to manufacturing issues. 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

Management plan:

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

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

- Clinicians will need to work with local 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>

This information should be shared with all health care professionals in primary, secondary or specialist healthcare services who prescribe, dispense or administer fluoxetine. To minimise the disruption this may cause locally in terms of patients seeking GP appointments, GP practices may want to consider using local IT systems to identify patients who may be impacted by this shortage and manage in accordance with this guidance.

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.