

20th 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 NHS Trust or 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>
- In order for pharmacies to dispense an unlicensed drug, FP10 prescriptions must indicate that an unlicensed special is required/prescribed by the GP. This could include the GP annotating the prescription with the following wording: **“special order”**.

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.

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

We hope this information is helpful and thank you for your assistance with this issue.

Yours sincerely,

DHSC Medicines Supply Team