

From the Chief Pharmaceutical Officer
Mrs Cathy Harrison



FOR ACTION

Chief Executives, Health and Social Care
Board/Business Services Organisation (*for
onward transmission to relevant staff*)
Assistant Director of Integrated Care, Head of
Pharmacy and Medicines Management, HSCB
(*for onward distribution to Community
Pharmacies*).
Head of General Medical Services, HSCB (*for
onward distribution to GP Practices*)
GP Medical Advisers, Health and Social Care
Board.

Castle Buildings
Stormont
BELFAST
BT4 3SQ
Tel: 028 90 523219
Email: cathy.harrison@health-ni.gov.uk

Date: 20th July 2020

Dear Colleagues,

UPDATE TO SERIOUS SHORTAGE PROTOCOL (SSP) – Fluoxetine 40mg capsules

I refer to my letter issued on 20 May 2020, when I wrote to notify you that due to a supply issue with fluoxetine 40mg capsules a Serious Shortage Protocol (SSP) had been put in place. The SSP was issued on 20 May 2020 with an end date of Monday 20 July 2020. I am writing to inform you that the SSP has been extended and will now end on Monday 10 August 2020.

See Annex A for the SSP. Details of the SSP are also available on the Business Services Organisation (BSO) dedicated page on its website www.hscbusiness.hscni.net/services/3063.htm

We are continuing to monitor the supply situation and will inform you promptly if there are any further developments with the SSP.

Action Required

All relevant staff should be made aware of this update to the SSP. I would ask the HSCB to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Cathy Harrison". The signature is written in a cursive style with a horizontal line extending to the right.

Cathy Harrison
Chief Pharmaceutical Officer

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP06

This SSP applies to the following medicine: **Fluoxetine 40mg capsules**

Name of medicine (including strength and formulation)	Fluoxetine 40mg capsules
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Fluoxetine 20mg capsules
Quantity of this formulation (if applicable)	Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription. For every 40mg capsule, the following quantity must be supplied in accordance with this protocol: 2 x 20mg fluoxetine capsules
Substitution results in a change to whether the use is licenced	No

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	England, Wales and Northern Ireland
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All NHS and private prescriptions. This protocol does not allow for the quantity supplied to be less than the number of days prescribed on the original prescription.
Criteria for inclusion	<ul style="list-style-type: none"> The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for fluoxetine 40mg capsules.

	<ul style="list-style-type: none"> The patient/carer consents to receiving the medicine supplied under this SSP. <p>All patients aged 18 years of age or above.</p>
Criteria for exclusion	<ul style="list-style-type: none"> The patient presents with a prescription for a medicine other than fluoxetine 40mg capsules. The patient presents a prescription which is not valid. The patient/carer does not consent to receiving the medicine(s) supplied under this SSP. Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative medicine under this SSP. Known previous hypersensitivity or severe adverse reaction to fluoxetine capsules or their excipients. Patients aged less than 18 years. Adults on a fluoxetine dose > 60mg daily.
Cautions including any relevant action to be taken	Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
Special considerations for specific populations of patients	<p>Switching the preparation (including different manufacturer) of the drug requires caution in certain patients who are considered at risk of deterioration due to the nocebo effect whereby patients believe that the exact preparation (including different manufacturer) of the drug is critical to their response.</p> <p>Patients considered unstable or at higher risk need to be referred back to their prescriber promptly for further advice.</p>
Action to be taken if the patient is excluded	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
Action to be taken if the patient or carer declines the supply	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

Valid from:	20 May 2020
Expiry date:	10 August 2020
Reference number:	SSP06
Version number:	2.0


Any queries regarding the content of this SSP which was issued by the Department of Health – Northern Ireland should be forwarded to communitypharmacy@health-ni.gov.uk

Change history

Version number	Change details	Date
2.0	Expiry date extended to 10 August 2020.	17/07/2020

2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at www.hscbusiness.hscni.net/services/3063.htm
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:			
Name	Position	Signature	Date
Minister Robin Swann	DOH Minister		20-07-20