

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP01

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Fluoxetine 10mg 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 10mg tablets OR Fluoxetine 20mg/5ml oral solution OR Fluoxetine 20mg/5ml oral solution sugar free (SF)
Quantity of this formulation (if applicable)	<p>Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription unless where oral solution (including SF version) is supplied, for which special container rules are applicable.</p> <p>For every 10mg capsule, the options in order of priority depending on what is available which can be supplied against this protocol are as follows:</p> <ul style="list-style-type: none"> • 1 x 10mg fluoxetine tablet OR • 2.5ml of fluoxetine 20mg/5ml oral solution SF* OR • 2.5ml of fluoxetine 20mg/5ml oral solution* <p>*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 (of 20mg/5ml oral solution / oral solution SF)</p>
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
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	<p>All NHS and private prescriptions.</p> <p>This protocol does not allow for the quantity supplied to be less than the number of days supplied on original prescription unless fluoxetine 20mg/5ml oral solution (and SF) where special container rules apply.</p>
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 10mg capsules. • The patient/carer consents to receiving the medicine supplied under this SSP. • All patients aged 8 years of age or above.
Criteria for exclusion	<ul style="list-style-type: none"> • The patient presents with a prescription for a medicine other than fluoxetine 10mg 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 alternative medicine under this SSP. • Known previous hypersensitivity or severe adverse reaction to fluoxetine oral solution (including sugar free), tablets or its excipients. • Where the pharmacist is aware that the patient has been hospitalised in an inpatient mental health unit within the last 6 months. • The patient has a specific requirement for capsules (e.g. capsules contents are opened and mixed in a vehicle for administration) and cannot swallow a tablet or liquid. • Children and adolescents on a fluoxetine dose > 20mg daily. • Adults on a fluoxetine dose > 40mg daily.
Cautions including any relevant action to be taken	<p>Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.</p>
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</p>

	<p>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> <p>Pharmacists should consider solid formulations as the preferred option for patients on monitored dosage systems e.g. dosette boxes / compliance aids.</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:	03 rd October 2019
Expiry date:	31 st October 2019
Reference number:	SSP01
Version number:	1.0

Any queries regarding the content of this SSP which was issued by the Secretary of State for Health and Social Care, should be addressed to NHS Prescription Services.

You can get in contact by:

Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk

Telephone: 0300 330 1349

Textphone: 18001 0300 330 1349

You can also write to us at:


Newcastle	Middlebrook	Wakefield
NHS Prescription Services Bridge House 152 Pilgrim Street Newcastle upon Tyne NE1 6SN	NHS Prescription Services Ridgway House Northgate Close Middlebrook Horwich Bolton BL6 6PQ	NHS Prescription Services 4th Floor Wakefield House Borough Road Wakefield WF1 3UB

Change history

Version number	Change details	Date

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 <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>.
- 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
Nicola Blackwood	Parliamentary Under Secretary of State for Innovation		02/10/2019

ADDENDUM

Supporting information on notifying other healthcare professionals

- Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.
- Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.
- Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.
- In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS 111 Directory of Service finder is a way for pharmacies to look up the email address of the patient's GP.