



Department
of Health &
Social Care



SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP033

Version Number:

This SSP applies to the following medicine

Name of medicine (including strength and formulation)	Paracetamol suppositories 120mg
Legal category	P

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Paracetamol suppositories 125mg
Quantity of this formulation (if applicable)	Total quantity supplied in accordance with this protocol is to be equivalent to the number of days supplied on original prescription. For every paracetamol 120mg suppository, the following quantity must – subject to the inclusion criteria below – be supplied in accordance with this protocol: 1 x paracetamol 125mg suppository
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 and Wales
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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/carer presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for paracetamol 120mg suppositories. • The patient/carer consents to receiving the medicine supplied in accordance with this SSP. • The patient/carer should only be supplied in accordance with this SSP if the pharmacist is satisfied they understand and are able to accommodate the switch.
Criteria for exclusion	<ul style="list-style-type: none"> • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the marginally higher strength medicine in accordance with this SSP. • The patient/carer presents with a prescription for a medicine other than paracetamol 120mg suppositories. • The patient/carer presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied in accordance with this SSP. • Patients who have had a previous allergic reaction to paracetamol 125mg suppositories or their excipients. • Patients considered to be unsuitable or at higher risk need to be referred back to their prescriber promptly for further advice.
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	As paracetamol 120mg suppositories are largely prescribed for infants and children, concerns may be raised by parents/carers about the slightly increased dose (5mg) of the alternative. For the average patient the slight increase in dose will not be clinically significant and it is negligible in the context of the overall dosing schedule. For example, in the 1-year-old (10kg) where the recommended dose is either 120mg or 125mg given every 4-6 hours with a maximum of 4 times in 24 hours this only constitutes a maximum of a 4% variation from usual dose, and as children get heavier this variation decreases further. However, there may be some patients where dose is critical and these should be referred back to the prescriber.

	If the pharmacist, using their professional judgement, considers that supplying the patient in accordance with the SSP would not be appropriate, the patient should be referred back to their prescriber promptly.
Action to be taken if the patient is excluded	If a patient/carer 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:	31/05/2022
Expiry date:	26/08/2022
Reference number:	SSP033
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>.
- **Pharmacists should note the requirements on packaging and labelling of products containing paracetamol set out in Part 4 of Schedule 25 of the Human Medicines Regulations 2012.**
- 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
Lord Syed Kamall	PUSS for Technology Innovation and Life Sciences		31/05/2022

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 Service Finder is a way for pharmacies to look up the email address of the patient's GP.