



Dear Colleague

SERIOUS SHORTAGE PROTOCOL: CEFALEXIN 500MG TABLETS

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for cefalexin 500mg tablets, from 6 August 2024 to 27 September 2024.

Background

2. Changes made to the Human Medicines Regulations 2012 and the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, the latter of which became effective from 31 October 2019, allow the use of Serious Shortage Protocols (SSPs).
3. An SSP is an additional tool to manage and mitigate medication shortages and may be used when other measures have been exhausted or are likely to be ineffective. There are two types of SSP; one that covers prescription only medicines and another that covers pharmacy and general sales list medicines and appliances.
4. Each SSP is individually developed and authorised clinically, to enable community pharmacists and dispensing doctors to dispense a different strength or formulation or alternative medicine or appliances in accordance with the protocol, rather than having to refer prescribing decisions back to the original prescriber. These protocols are time limited.
5. Community pharmacists are expected to use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute a person's prescribed medicine using the SSP. The person will also have to agree to the alternative supply.

8 August 2024

Addresses

For action

Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information

Directors of Pharmacy
NHS Medical Directors

Enquiries to:

Pharmacy Team
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St Andrew's House
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Email:

PharmacyTeam@gov.scot

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6. Certain classes of medicines, for example cytotoxic medicines, biologics, anti-epileptic medicines and certain antipsychotic medicines, are not considered to be suitable for SSPs due to concerns about ensuring bioequivalence. In these cases, people should be referred back to the prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.
7. The addition of new SSPs and any amendments or extensions to existing SSPs are documented on the NHS Business Services Authority website using the following link: [Serious shortage protocols \(SSPs\) | NHSBSA](#).

Medicine supply situation requiring the use of an SSP

8. A supply issue with cefalexin 500mg tablets has been identified. In order to manage stock supplies fairly and effectively, there is a UK-wide SSP in place, which allows community pharmacists to substitute a prescription of the noted product with the same quantity of cefalexin 500mg **capsules**. This SSP can be accessed using the following link: [SSP072 Cefalexin 500mg tablets 01082024.pdf \(nhsbsa.nhs.uk\)](#)

Operational overview

9. Between 6 August 2024 and 27 September 2024, for patients presenting with an NHS or private prescription for a supply of cefalexin 500mg tablets, community pharmacists may substitute this product with the same quantity of cefalexin 500mg **capsules** in accordance with this SSP.
10. Total quantity supplied under this protocol is to be equivalent to the number of days supplied on the original prescription.
11. Community pharmacists are asked to review and familiarise themselves with the scope and the clinical situation to which this SSP applies, as outlined in the guidance provided within [SSP 072](#).
12. Pharmacists are asked to ensure that the patient/carer is aware that the capsule form of cefalexin may contain gelatine. Pharmacists may wish to check the patient information leaflet or summary product characteristics if patients are concerned.
13. Patients who have had a previous allergic reaction to cefalexin 500mg capsules or their excipients, along with patients who are considered to be unstable or at higher risk are excluded from the scope of this SSP. Patients considered unsuitable for this SSP need to be referred back to their prescriber promptly for further advice.
14. If a patient or their carer declines to receive the medicine under this SSP, a pharmacist should use their professional judgement to determine if other courses of action are appropriate whilst taking into consideration wider supply issues. If this does not address their concerns, the patient should be referred back to their prescriber for advice.
15. If a 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.

Additional information

16. Patients from any UK Nation who present their prescriptions for cefalexin 500mg tablets are eligible to receive a substituted product under the terms of this SSP 072.
17. The scope of this SSP 072 applies to valid prescriptions that meets the requirements of the Human Medicine Regulations 2012, so it would cover both NHS and private prescriptions, unless where it stated otherwise on the SSP itself.
18. The supply in accordance with this SSP 072 only allows supply of specific substitutions up to the duration of treatment prescribed. However, if a pharmacist thinks that an alternative product, other than those specified, would be suitable for the patient they should either contact the prescriber to discuss this (with the patient's consent) or direct the patient back to the prescriber.
19. If a 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.
20. In the event that a pharmacist concludes that it is reasonable and appropriate to dispense in accordance with the SSP, but the patient persists in refusing to accept the option of a substituted product, the pharmacist may advise the patient that they will dispense in accordance with the SSP or not at all if that is in accordance with their professional judgement.
21. The patient retains the right to either accept the professional decision of a pharmacist or to ask for their prescription to be returned to them.

Supporting information on notifying other healthcare professionals

22. Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical Services Regulations.
23. Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would be expected within the next working day, but further guidance would be given in any case where this applied.
24. 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.

Fees and Endorsements

25. When an SSP is introduced, the pharmacist should use the Other endorsement function quoting SSP and the relevant reference number – in this case add SSP 072. A community pharmacy contractor will receive a multiplier per item of 5 (x5), via the dispensing pool, for any necessary supply in accordance with SSPs. Endorsements must be made in line with the SSP to be eligible for payment.

26. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 072' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

27. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at PharmacyTeam@gov.scot.

Action

28. **Health Boards are asked to note the contents of this Circular and to bring it to the attention of community pharmacy contractors on their Pharmaceutical Lists and Area Pharmaceutical Committees. This Circular should also be brought to the attention of General Practices.**

Yours sincerely



Alison Strath

Chief Pharmaceutical Officer