Chief Medical Officer Directorate

Pharmacy and Medicines Division



Dear Colleague

SERIOUS SHORTAGE PROTOCOL: NIFEDIPINE (ADIPINE® XL) 60MG MODIFIED-RELEASE TABLET

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for nifedipine (Adipine® XL) 60mg modified-release tablet, from 19 December 2025 to 6 February 2026.

Background

- 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.

23 December 2025

Addresses

For action
Chief Executives, NHS Boards
Director Practitioner Services,
NHS NSS

For information
Directors of Pharmacy
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Enquiries to:

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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: <u>Serious shortage protocols</u> (SSPs) | NHSBSA.

Medicine supply situation requiring the use of an SSP

8. A supply issue with nifedipine (Adipine® XL) 60mg modified-release tablet 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 a different brand of nifedipine modified-release product. This SSP can be accessed using the following link: SSP085 Adipine XL 60mg MR tabs 19122025 - signed.pdf.

Operational overview

- 9. Between 19 December 2025 and 6 February 2026, for patients presenting with an NHS or private prescription for a supply of nifedipine (Adipine[®] XL) 60mg modified-release tablet, community pharmacists may substitute this product with any of the Nifedipine products noted below, for eligible patients, in accordance with this SSP:
 - nifedipine (Adanif[®] XL) 60mg modified-release tablet OR
 - nifedipine (Coracten® XL) 60mg modified-release tablet OR
 - nifedipine (Coracten[®] XL) 30mg modified-release capsule
- 10. Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription. This protocol does **not** allow for the quantity supplied to be less than the number of days prescribed on original prescription.
- 11. For every nifedipine (Adipine® XL) 60mg modified-release tablet, the following quantity must be supplied in accordance with this protocol noting that the second option is preferred over the third option:
 - 1 x nifedipine (Adanif® XL) 60mg modified-release tablet OR
 - 1 x nifedipine (Coracten[®] XL) 60mg modified-release tablet OR
 - 2 x nifedipine (Coracten® XL) 30mg modified-release capsule
- 12. Pharmacists should note that the order of substitutions reflects preferential use of regimen that most closely matches existing treatment, where available.

- 13. Pharmacists should counsel patients on a change in number of dose units to be taken if substituting with 2 x nifedipine (Coracten® XL) 30mg modified-release capsules.
- 14. Pharmacists must ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP
- 15. Pharmacists will need to discuss with the patient/carer whether they have used any of the alternative brands listed in the SSP before. Where appropriate the patient/carer should be made aware of the change and be advised that they may require closer monitoring initially to ensure blood pressure/angina symptoms remain controlled, and to report any adverse effects. If they have concerns, they should contact their doctor.
- 16. Where the patient/carer is supplied with Coracten® XL modified-release capsules, pharmacists are asked to ensure that the patient/carer is made aware that this product contains gelatine. Pharmacists may wish to check the patient information leaflet or summary product characteristics (SmPC) if patients are concerned.
- 17. 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 085.
- 18. If a patient does not meet the inclusion criteria within this SSP then they should be referred back to their prescriber promptly.
- 19. If a patient or their carer/guardian declines to receive the medicine under this SSP, the 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.
- 20. This SSP 085 only applies to prescriptions for nifedipine (Adipine® XL) 60mg modified-release tablet. Supply in accordance with this SSP only allows supply of a specific substitution up to the duration of treatment prescribed. However, if the pharmacist thinks that an alternative product, 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.
- 21. 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.

Additional information

- 22. Patients from any UK Nation who present their prescriptions for nifedipine (Adipine® XL) 60mg modified-release tablets are eligible to receive a substituted product under the terms of this SSP 085.
- 23. The scope of this SSP 085 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.

- 24. 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.
- 25. 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.
- 26. This SSP 085 only applies to prescriptions for nifedipine (Adipine® XL) 60mg modified-release tablets. If the prescription states the 30mg strength of nifedipine (Adipine® XL) modified-release tablets, then pharmacists should consider if supply in accordance of SSP 084 for nifedipine (Adipine® XL) 30mg modified-release tablet would be appropriate.

Supporting information on notifying other healthcare professionals

- 27. 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.
- 28. 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.
- 29. 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

- 30. 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 085. 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.
- 31. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 085' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

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

Action

33. 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