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Chief Medical Officer Directorate
Pharmacy and Medicines Division

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Addresses

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

For information
Directors of Pharmacy
NHS Medical Directors

Enquiries to:

Pharmacy Team
1st Floor East Rear
St Andrew's House
EDINBURGH
EH1 3DG

Email:
PharmacyTeam@gov.scot

www.gov.scot

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: ISOSORBIDE MONONITRATE (MONOMIL® XL 60MG) MODIFIED-RELEASE TABLET

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for isosorbide mononitrate (Monomil® XL 60mg) modified-release tablet, from 6 September 2024 to 17 January 2025.

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.

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 isosorbide mononitrate (Monomil® 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 the same quantity but different brand of isosorbide mononitrate 60mg modified-release tablet. This SSP can be accessed using the following link: SSP075 Monomil XL 60 06092024.pdf

Operational overview

9. Between 6 September 2024 and 17 January 2025, for patients presenting with an NHS or private prescription for a supply of isosorbide mononitrate (Monomil® XL 60mg) modified-release tablet, community pharmacists may substitute this product with the **same quantity** of any of the isosorbide mononitrate products noted below, for eligible patients, in accordance with this SSP:

   - Isosorbide mononitrate (Isotard® 60XL) 60mg modified-release tablet
     OR
   - Isosorbide mononitrate (Medomon® XL) 60mg modified-release tablet
     OR
   - Isosorbide mononitrate (Relosorb® XL) 60mg modified-release tablet
     OR
   - Isosorbide mononitrate (Tardisc®XL 60) 60mg modified-release tablet

10. Total quantity supplied in accordance with this protocol is to be equivalent to the number of days treatment prescribed on the original prescription.

11. For every isosorbide mononitrate (Monomil® XL 60mg) modified-release tablet, the following quantity must be supplied in accordance with this protocol: 1 x any tablet from the list of eligible products noted above.

12. Patients should be made aware of the change and be warned of possible adverse events that they may experience particularly in the first few days. The most important is hypotension (low blood pressure) as well as faster heart rate. Also, headache may get worse. If they have concerns, they should contact their doctor.

13. Patients with known previous hypersensitivity or severe adverse reaction to one of the alternative tablets allowed in accordance with this protocol, or their excipients do not meet the inclusion criteria of this protocol. Similarly, patients aged less than 18 years are excluded from this protocol.

14. If a patient does not meet the inclusion criteria within this SSP then they should be referred back to their prescriber promptly.

15. 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 075.

16. 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.

17. This SSP 075 only applies to prescriptions for isosorbide mononitrate (Monomil® 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.

18. 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

19. Patients from any UK Nation who present their prescriptions for isosorbide mononitrate (Monomil® XL 60mg) modified-release tablets are eligible to receive a substituted product under the terms of this SSP 075.

20. The scope of this SSP 075 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.

21. Community pharmacists should 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 warned of possible adverse events that they may experience particularly in the first few days. Pharmacists must refer to the cautions listed in the SSP 075, including any relevant actions that need to be taken.

22. This SSP 075 only applies to prescriptions for isosorbide mononitrate (Monomil® XL 60mg) modified-release tablets. If the prescription states one of the following brands, then pharmacists should consider if supply in accordance any of the following SSPs would be appropriate:
    - SSP 073 for Chemydur® 60XL modified-release tablets
    - SSP 074 for Monomax® XL 60mg modified-release tablets.

Supporting information on notifying other healthcare professionals

23. 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.

24. 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.

25. 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

26. 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 075. 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.

27. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 075' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

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

Action

29. **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