

**From the Chief Pharmaceutical Officer
Professor Cathy Harrison**



Department of
Health

An Roinn Sláinte

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FOR ACTION

Deputy Secretary, Strategic Planning and Performance Group (*for onward transmission to relevant staff*)

Chief Executive, Business Services Organisation (*for onward transmission to relevant staff*)

Assistant Director of Integrated Care, Head of Pharmacy and Medicines Management, SPPG (*for onward distribution to Community Pharmacies*).

Head of General Medical Services, SPPG (*for onward distribution to GP Practices*)

GP Medical Advisers, Strategic Planning and Performance Group.

Dear Colleagues,

SERIOUS SHORTAGE PROTOCOLS– ISOSORBIDE MONONITRATE 60MG PREPARATIONS— CHEMYDUR® 60XL TABLETS, MONOMAX® XL 60MG TABLETS, MONOMIL® XL 60MG TABLETS AND NYZAMAC® SR 60MG CAPSULES

Serious shortage protocols (SSPs) under the Human Medicines Regulations 2012 (HMRs) are an additional tool to manage and mitigate medicines shortages. An SSP enables community pharmacists to supply a specified medicine in accordance with a protocol rather than a prescription, without needing to seek authorisation from the prescriber, saving time for patients, pharmacists and prescribers. They are used in the case of a serious shortage, where a medicine would be likely to be out of stock for some time, and if, in the opinion of ministers, it would help manage the supply situation.

I am writing to inform you that in response to supply concerns across the UK regarding the availability of the following **isosorbide mononitrate 60mg preparations, Chemydur® 60XL tablets, Monomax® XL 60mg tablets, Monomil® XL 60mg tablets** and **Nyzamac® SR 60mg tablets**, the Department of Health of Social Care (DHSC) has issued **four** SSPs.

SSP073- Chemydur® 60XL tablets, **SSP074**- Monomax® XL 60mg tablets, **SSP075**- Monomil® XL 60mg tablets and **SSP076**- Nyzamac® SR 60mg tablets, are due to expire on **various dates between 27 September 2024 and 17 January 2025**. A summary of the SSPs, including the expiry dates and alternative products to be supplied, can be found in the table below. Pharmacists should refer to the latest version of the SSPs which are available on the Business Services Organisation (BSO) dedicated page on its website:

<https://bso.hscni.net/directorates/operations/family-practitioner-services/pharmacy/contractor-information/drug-tariff-and-related-materials/serious-shortage-protocols-ssps/>.

SSP Number	Medicine Affected	Expiry Date	Alternatives
SSP073	Chemydur® 60XL Tablet	27 September 2024	Isotard® 60XL 60mg Tablet
SSP074	Monomax® XL 60mg Tablet	18 October 2024	OR Medomon® XL 60mg Tablet
SSP075	Monomil® XL 60mg Tablet	17 January 2025	OR
SSP076	Nyzamac® SR 60mg Capsule	8 November 2024	Relosorb® XL 60mg Tablet OR Tardisc® XL 60 Tablet

These SSPs authorised by the Secretary of State on behalf of the four UK nations, has been developed by clinicians and provides pharmacists with procedures to follow in providing this suitable alternative product to help reduce the number of patients having to return to their prescriber for a replacement prescription.

Key Points:

- The SSPs only permit the substitution of **every tablet or capsule of the isosorbide mononitrate 60mg preparation listed in the 'Name of the medicine (including formulation and strength' box** in the specific SSP with **one isosorbide mononitrate 60mg tablet brand listed in the 'Name of**

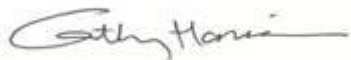
medicine (including formulation and strength) to be supplied' box in the SSP, and does not allow for the quantity supplied to be less than the number of days prescribed on the original prescription.

- 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.
- Community pharmacists should use their professional skill and judgement to decide whether it is reasonable and appropriate to substitute the patient's prescribed order for a supply under this SSP. The patient/carer will also need to agree to supply under the SSP.
- Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
- Pharmacists must ensure that the patient's prescriber and/or GP practice is notified when supplying a patient in accordance with this SSP as soon as practically possible, and should aim to forward these details within 3 working days Please refer to ['Outline of Operational Guidance for Dispensers in response to issue of a Serious Shortage Protocol'](#) on the BSO website for more information.
- If a patient/carer declines to receive the medicine under these protocols, 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/carer should be referred back to their prescriber for advice.

Action Required

All relevant staff should be made aware of these SSPs. I would ask the SPPG to bring this information to the attention of GP Practices and Community Pharmacists directly.

Yours sincerely,



Professor Cathy Harrison
Chief Pharmaceutical Officer