

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



Department of
Health

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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 PROTOCOL EXTENSION – MONOMIL® XL 60MG TABLETS (ISOSORBIDE MONONITRATE 60MG MODIFIED RELEASE TABLETS)

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 light of ongoing supply concerns across the UK regarding the availability of Monomil® XL 60mg tablets, a decision has been made to extend the duration of the current SSP, [SSP059](#), to enable community pharmacists in Northern Ireland to supply patients affected with an alternative.

[SSP059](#) issued by the Department of Health and Social Care (DHSC) and authorised by the Secretary of State on behalf of the four UK nations will now **expire on Friday 7 June 2024**.

It is important to note that there are two groups of alternatives listed in the SSP, Group 1 and Group 2, under the section 'Name of medicine (including formulation and strength) to be supplied'. **Pharmacies should supply from the medicines in Group 1 in the first instance, supplying from Group 2 where those products in Group 1 are not available. This is based on supply volumes to help support supply chains and not clinical interchangeability.**

Group 1

Chemydur® 60XL 60mg modified release tablet **OR**

Relosorb® XL 60mg modified release tablet **OR**

Isotard® 60XL 60mg modified release tablet.

Group 2

Monomax® XL 60mg modified release tablet **OR**

Monosorb® XL60 60mg modified release tablet **OR**

Tardisc® XL60 60mg modified release tablet.

The SSP provides that for every Monomil® XL 60mg tablet originally prescribed, one of any tablet from the list above in Group 1 or Group 2 if applicable can be supplied.

Details of this SSP will also be 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/>.

Key points:

- This protocol **does not allow** for the quantity supplied to be less than the number of days prescribed on the original prescription.
- Should the quantity on the prescription be unclear, the pharmacist should consult with the patient and use their professional skill and judgement to make an appropriate supply under this SSP. Pharmacists should refer to the relevant Summary of Product Characteristics (SPC) and Patient Information Leaflets (PIL) to inform these decisions. The patient/carer will also need to agree to supply under the SSP.
- 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

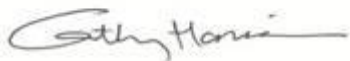
important is hypotension (low blood pressure) as well as faster heart rate. Also, headache may get worse. If they have concerns, they should contact their doctor.

- 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.
- 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 this SSP. 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