



SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP059

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Isosorbide mononitrate (Monomil [®] XL) 60mg modified-release tablet
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	<p>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 and not clinical interchangeability.</p> <p>Group 1</p> <p>Isosorbide mononitrate (Chemydur[®] 60XL) 60mg modified-release tablet</p> <p>OR</p> <p>Isosorbide mononitrate (Relosorb[®] XL) 60mg modified-release tablet</p> <p>OR</p> <p>Isosorbide mononitrate (Isotard[®] 60XL) 60mg modified-release tablet</p> <p>Group 2</p>
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	<p>Isosorbide mononitrate (Monomax[®] XL) 60mg modified-release tablet</p> <p>OR</p> <p>Isosorbide mononitrate (Monosorb[®] XL 60) 60mg modified-release tablet</p> <p>OR</p> <p>Isosorbide mononitrate (Tardisc[®]XL 60) 60mg modified-release tablet</p>
Quantity of this formulation (if applicable)	<p>Total quantity supplied under this protocol to be equivalent to the number of days supplied on the original prescription.</p> <p>For every isosorbide mononitrate (Monomil[®] XL) 60mg modified release tablet, the following quantity must be supplied in accordance with this protocol:</p> <p>1 x any tablet from the list in the 'Name of medicine (including formulation and strength) to be supplied' box above.</p>
Substitution results in a change to whether the use is licenced	No

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	UK-wide
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	<p>All NHS and private prescriptions.</p> <p>This protocol does not allow for the quantity supplied to be less than the number of days prescribed on the original prescription.</p>
Criteria for inclusion	<ul style="list-style-type: none"> The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for isosorbide mononitrate (Monomil[®] XL) 60mg modified release tablets.

	<ul style="list-style-type: none"> • The patient/carer consents to receiving the medicine supplied under this SSP. • All patients aged 18 years of age or above.
Criteria for exclusion	<ul style="list-style-type: none"> • The patient presents with a prescription for a medicine other than isosorbide mononitrate (Monomil® XL) 60mg modified release tablets. • The patient presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied under this SSP. • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative medicine under this SSP. • Known previous hypersensitivity or severe adverse reaction to one of the alternative tablets allowed in accordance with this protocol, or their excipients. • Patients aged less than 18 years.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • 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. • Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
Special considerations for specific populations of patients	Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative medicine in accordance with this SSP.
Action to be taken if the patient is excluded	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
Action to be taken if the patient or carer declines the supply	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

Valid from:	26/03/2024
Expiry date:	03/05/2024
Reference number:	SSP059
Version number:	1.0

Any queries regarding the content of this SSP which was issued by the Secretary of State for Health and Social Care, should be addressed to NHS Prescription Services.

You can get in contact by:

Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk

Telephone: 0300 330 1349

Textphone: 18001 0300 330 1349

You can also write to us at:


Newcastle	Middlebrook	Wakefield
NHS Prescription Services Bridge House 152 Pilgrim Street Newcastle upon Tyne NE1 6SN	NHS Prescription Services Ridgway House Northgate Close Middlebrook Horwich Bolton BL6 6PQ	NHS Prescription Services 4th Floor Wakefield House Borough Road Wakefield WF1 3UB

Change history

Version number	Change details	Date

2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>.
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:			
Name	Position	Signature	Date
Andrew Stephenson	Minister of State for Health		26/03/2024

ADDENDUM

Supporting information on notifying other healthcare professionals

- 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 2013.
- 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.
- 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.
- In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS Service Finder is a way for pharmacies to look up the email address of the patient's GP.

Northern Ireland

- 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.