

Dear Colleague

SERIOUS SHORTAGE PROTOCOL: CLARITHROMYCIN 250MG/5ML ORAL SUSPENSION

Purpose

1. To advise of a Serious Shortage Protocol (SSP) in place for Clarithromycin 250mg/5ml oral suspension, from 6 April 2023 to 28 April 2023.

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.

21 April 2023

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

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 Clarithromycin 250mg/5ml oral suspension 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 the noted product with Clarithromycin 250mg tablets. This SSP can be accessed using the following link: [SSP054 Clarithromycin 250mg-5ml oral suspension final 06042023.pdf \(nhsbsa.nhs.uk\)](#)

Operational overview

9. Between 6 April 2023 and 28 April 2023, for patients presenting with an NHS or private prescription for a supply of Clarithromycin 250mg/5ml oral suspension, community pharmacists may substitute this product with Clarithromycin 250mg tablets.
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 5ml of Clarithromycin 250mg/5ml oral suspension, the following quantity must be supplied in accordance with this protocol: **1 x Clarithromycin 250mg**.
12. 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 054](#).
13. When a substitution is made, pharmacists need to ensure that the patient's prescriber and/or GP practice is notified in accordance with this SSP.
14. Patients considered to be unsuitable or at higher risk as outlined in the "Criteria for exclusion" section of [SSP 54](#) need to be referred back to their prescriber promptly for further advice.

Additional information

15. Where patients are unable to swallow whole tablets, pharmacists should counsel patients/carers on alternative methods e.g. crushing tablets to give solid oral dosage forms which is included in the addendum at the end of this protocol. Please note that use in this way may be outside the product licence and is thus "off-label".

16. 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.
17. If a patient/carer declines to receive medicine under this SSP, then they should be referred back to their prescriber promptly.
18. If the pharmacist thinks that an alternative product not listed in this SSP 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.

Supporting information on notifying other healthcare professionals

19. 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.
20. 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.
21. 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.
22. 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.

Switching from liquid to solid Clarithromycin

23. When the pharmacist deems it appropriate to substitute to the tablet form in accordance with this SSP and further guidance is required on off-label administration to aid swallowing, pharmacists should counsel patients/carers in line with the guidance provided by the Specialist Pharmacy Service: [Using solid oral dosage form antibiotics in children](#).

Fees and Endorsements

24. 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 054. 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.

25. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 054' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

Enquiries

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

Action

27. **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