



Dear Colleague

## **SERIOUS SHORTAGE PROTOCOL: CREON® 25000 GASTRO-RESISTANT CAPSULES**

### **Purpose**

1. To advise of a Serious Shortage Protocol (SSP) in place for Creon® 25000 gastro-resistant capsules, from 24 May 2024 to 22 November 2024.

### **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.

29 May 2024

### **Addresses**

#### For action

Chief Executives, NHS Boards  
Director Practitioner Services,  
NHS NSS

#### For information

Directors of Pharmacy  
NHS Medical Directors

### **Enquiries to:**

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

Email:

[PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot)

[www.gov.scot](http://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 Creon® 25000 gastro-resistant capsules 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 restrict the total quantity supplied under this protocol to one month's supply of the prescribed medicine. This is applicable where supplies are available, but the prescription is for more than one month's supply.

### **Operational overview**

9. Between 24 May 2024 and 22 November 2024, for patients presenting with an NHS or private prescription for more than one month's supply of Creon® 25000 gastro-resistant capsules, community pharmacist may limit the total quantity supplied under this protocol to be equivalent to one month's supply of the prescribed medicine.
10. If a patient or their carer 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 to their prescriber for advice.
11. For patients with a prescription for one month or less, pharmacists are advised to supply the full amount prescribed if available. If the full amount prescribed is not available, the patient should be referred to a pharmacy that has enough stock or to be referred to their prescriber.
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 061](#).
13. 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 to their prescriber promptly.

### **Additional information**

14. Patients from any UK Nation who present their prescriptions for Creon® 25000 gastro-resistant capsules are eligible to receive a lower quantity under the terms of this SSP 061.

15. The scope of this SSP 061 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.
16. The supply in accordance with this SSP only allows supply of a one-month quantity when the prescription is for a longer duration of treatment. It does not allow the supply of a different product. 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.
17. Where it is not clear from the prescription what constitutes a one month supply, the pharmacist will need to discuss with the patient and use their professional judgment.
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 to their prescriber promptly.

#### 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 Services Regulations and any Health Board's local arrangements.
20. 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.

#### **Fees and Endorsements**

22. 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 061. 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.
23. The paper form should be endorsed PMR with details added of what was supplied as well as 'SSP 061' annotated. This is to ensure accurate reimbursement for non-barcoded forms or where an electronic claim message is unavailable.

## Enquiries

24. For any queries on the detail of this SSP, please contact the Scottish Government Pharmacy Team at [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot).

## Action

25. **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