Department of Health & Social Care

NHS

SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP034

Version Number:

This SSP applies to the following medicine

Name of medicine (including strength and formulation)	Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pressurised metered dose inhaler (pMDI)
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Fluticasone 125microgram/Salmeterol 25microgram pressurised metered dose inhaler (pMDI)
Quantity of this formulation (if applicable)	Total quantity supplied in accordance with this protocol is to be equivalent to the number of days supplied on original prescription. For every Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pressurised metered dose inhaler (pMDI), the following quantity must – subject to the inclusion criteria below – be supplied in accordance with this protocol: 1 x Fluticasone 125microgram/Salmeterol 25microgram pMDI
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	England and Wales

Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	All NHS and private prescriptions. This protocol does not allow for the quantity supplied to be less than the number of days prescribed on the original prescription
Criteria for inclusion	• The patient/carer presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pressurised metered dose inhaler (pMDI). • The patient/carer consents to receiving the medicine supplied in accordance with this SSP. • The patient/carer should only be supplied in accordance with this SSP if the pharmacist is satisfied they understand and are able to accommodate the switch. • All patients aged 12 years or over
Criteria for exclusion	• Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive the alternative inhaler in accordance with this SSP. • The patient/carer presents with a prescription for a medicine other than Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pressurised metered dose inhaler (pMDI). • The patient/carer presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied in accordance with this SSP. • Patients who have had a previous allergic reaction to Fluticasone 125microgram/Salmeterol 25microgram pMDI or their excipients. • Patients considered to be unsuitable or at higher risk need to be referred back to their prescriber promptly for further advice. • All patients aged under 12 years.
Cautions including any relevant action to be taken	Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.

Special considerations for specific populations of patients	Ensure that the patient is not intolerant to any of the excipients and appropriate counselling is undertaken after switching inhaler treatment. Note that some of the alternatives contain ethanol – see the table at **Annex A** Combisal® (Fluticasone 125microgram / Salmeterol 25microgram) pressurised metered dose inhaler (pMDI) is licensed for the treatment of asthma in patients from age 12 years upwards. It is compatible with the AeroChamber Plus® spacer. If a patient is aged between 12 and 17 years old, the pharmacist should supply an alternative Fluticasone 125microgram/Salmeterol 25microgram pMDI licensed for that age group as set out in **Annex A**, below. If a patient uses a spacer with their inhaler, the pharmacist should ascertain whether the substituted inhaler is compatible with the patient's spacer, as set out in the table at **Annex A**. If no compatible inhaler is available, the pharmacist should supply the patient with a spacer compatible with the inhaler free of charge and claim reimbursement when claiming for the SSP. (See the accompanying endorsement guidance for further information). 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. To note: all relevant products are special containers and will be reimbursed accordingly.
Action to be taken if the patient is excluded	If a patient/carer 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:	22/07/2022
Expiry date:	19/08/2022
Reference number:	SSP034
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
Lord Syed Kamall	PUSS for Technology Innovation and Life Sciences		22/07/2022

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.

- 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.

Annex A: Alternative Fluticasone 125microgram/Salmeterol 25microgram pMDIs

Alternative inhalers	Compatible spacer	Licensed age group	Contains ethanol
Fluticasone 125microgram / Salmeterol 25microgram (Aloflute®) pMDI	AeroChamber Plus®	18+	Yes
Fluticasone 125microgram / Salmeterol 25microgram (Sereflo®) pMDI	Manufacturer advises spacer devices are not compatible – if spacer device required switch to alternative fixed-dose combination preparation	18+	No
Fluticasone 125microgram / Salmeterol 25microgram (Seretide® 125 evohaler) pMDI	Volumatic®	12+	No
Fluticasone 125microgram / Salmeterol 25microgram (Sirdupla®) pMDI	AeroChamber Plus®	18+	Yes