



# SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP011

This SSP applies to the following medicine:

<b>Name of medicine (including strength and formulation)</b>	Competact® 15mg/850mg tablets, also prescribed as pioglitazone 15mg/metformin 850mg tablets
<b>Legal category</b>	POM

## 1. Details of medication to be supplied under this SSP

<b>Name of medicine (including formulation and strength) to be supplied</b>	Pioglitazone 15mg tablets and metformin 850mg tablets
<b>Quantity of this formulation (if applicable)</b>	Total quantity supplied under this protocol to be equivalent to the number of days supplied on original prescription.  For every Competact® 15mg/850mg tablet or pioglitazone 15mg/metformin 850mg tablet, the following quantity must be supplied in accordance with this protocol:  1 x pioglitazone 15mg tablet AND 1 x metformin 850mg tablet
<b>Substitution results in a change to whether the use is licenced</b>	No

## Scope for which this Serious Shortage Protocol (SSP) applies

<b>The SSP applies to the following parts of the UK</b>	England, Wales and Scotland
---	-----------------------------

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

<b>Scope of SSP</b>	All NHS and private prescriptions.
---------------------	------------------------------------

	This protocol does <b>not</b> allow for the quantity supplied to be less than the number of days prescribed on original prescription.
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for pioglitazone 15mg/metformin 850mg tablets or Competact® 15mg/850mg tablets.</li> <li>• The patient/carer consents to receiving the medicine supplied under this SSP.</li> <li>• The patient should only be supplied in accordance with this SSP if the pharmacist is satisfied the patient understands and is able to accommodate the switch from one to two tablets.</li> <li>• All patients aged 18 years of age or above.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative medicine under this SSP.</li> <li>• The patient presents with a prescription for a medicine other than pioglitazone 15mg/metformin 850mg tablets or Competact® 15mg/850mg tablets.</li> <li>• The patient presents a prescription which is not valid.</li> <li>• The patient/carer does not consent to receiving the medicine(s) supplied under this SSP.</li> <li>• Patients who have had a previous allergic reaction to pioglitazone 15mg tablets or metformin 850mg tablets, or their excipients.</li> <li>• All patients aged 18 years or age or under.</li> <li>• Patients considered to be unstable or at higher risk need to be referred back to their prescriber promptly for further advice.</li> </ul>
<b>Cautions including any relevant action to be taken</b>	Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.
<b>Special considerations for specific populations of patients</b>	<p>Switching the preparation (including different manufacturer) of the drug requires caution in certain patients who are considered at risk of deterioration due to their belief that the exact preparation (including different manufacturer) of the drug is critical to their response.</p> <p>Patients considered unstable or at higher risk need to be referred back to their prescriber promptly for further advice.</p>
<b>Action to be taken if the patient is excluded</b>	If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.

<b>Action to be taken if the patient or carer declines the supply</b>	If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.
---	--

<b>Valid from:</b>	24 March 2021
<b>Expiry date:</b>	7 May 2021
<b>Reference number:</b>	SSP011
<b>Version number:</b>	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](mailto:nhsbsa.prescriptionservices@nhsbsa.nhs.uk)

**Telephone:** 0300 330 1349

**Textphone:** 18001 0300 330 1349

You can also write to us at:

<b>Newcastle</b>	<b>Middlebrook</b>	<b>Wakefield</b>
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

<b>Version number</b>	<b>Change details</b>	<b>Date</b>

## 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.

<b>Ministerial ratification by:</b>			
<b>Name</b>	<b>Position</b>	<b>Signature</b>	<b>Date</b>
Lord Bethell	Minister for Innovation, DHSC		24.03.2021

## **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 111 Directory of Service finder is a way for pharmacies to look up the email address of the patient's GP.