

## **Standard Operating Procedure (SOP) for the review of Dosulepin prescribing**

*This is a CCG SOP that would be used by the CCG staff to complete this piece of work. If you want to utilise this, please adapt it to meet your own needs in practice.*

### **Introduction**

NHS England produced guidance for CCG's on items which should not be routinely prescribed in primary care, either due to a lack of clinical evidence to support their use, more cost-effective options being available or because there are significant safety concerns. The guidance, [Items which should not routinely be prescribed in primary care v2.1.pdf](#), includes Dosulepin due to significant safety concerns associated the use of this medicine, namely **toxicity in overdose** and an **increased cardiac risk**.

For reference, the advice to CCGs is the following:

- 
- Advise CCGs that prescribers in primary care should not initiate Dosulepin for any new patient.
  - Advise CCGs to support prescribers in deprescribing Dosulepin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
  - Advise CCGs that if, in exceptional circumstances, there is a clinical need for Dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with multi-disciplinary team and/or other healthcare professional.
- 

It is important to note that there are no clear guidelines on the switching of anti-depressants, thus where there is uncertainty/difficulty with the switch process, specialist advice must be sought. The following table has been extracted from PrescQIPP bulletin 126 on Dosulepin:

## Switching and stopping options

The choice of a potential alternative antidepressant should be discussed with the patient and should take into account their depressive symptoms, relative side effects, physical illness and interactions with any other prescribed medicines.<sup>4-6,8</sup>

A suggested withdrawal regimen for dosulepin is:

Current dose	Week 1	Week 2	Week 3	Week 4
150mg/day	100mg/day	50mg/day	25mg/day	STOP

Switching dosulepin to a SSRI:<sup>6</sup>

- Gradually reduce the dose of dosulepin to 25-50mg/day as per the above withdrawal regimen, then add in the SSRI at the usual starting dose. Then slowly withdraw the remaining dosulepin over 5-7 days.
- Patients under the care of a specialist should be referred back to consider suitability of switching in partnership.
- Alternative non-antidepressant options may be suitable for patients taking dosulepin for other indications.

The withdrawal regimen can be adapted to suit individual patient needs. Please refer to the original PrescQIPP bulletin for further information.

Additionally, please see the following information from NICE CKS on switching TCA's (Tricyclic Antidepressants) to alternative antidepressants. Access <https://cks.nice.org.uk/topics/depression/prescribing-information/switching-antidepressants/> for further information.

	Switching to:				
Switching from:	TCA (except clomipramine)	SSRI (citalopram, escitalopram, paroxetine or sertraline)	SNRI (duloxetine, venlafaxine)	Fluoxetine	Mirtazapine
TCA (except clomipramine)	Direct switch possible	Gradually reduce the dose of TCA to 25-50 mg daily [SPS, 2019c] or half the usual dose [Taylor, 2018]. Start SSRI then slowly withdraw TCA over next 5-7 days [SPS, 2019c]	Cross-taper cautiously starting with low dose SNRI	Halve dose of TCA, add fluoxetine and then slowly withdraw TCA	Cross-taper cautiously

An interpretation of Maudsley guidelines, NICE CKS & the BNF is provided in the Nottingham Dosulepin Deprescribing information sheet, accessible via <https://www.nottinghamshiremedicinesmanagement.nhs.uk/media/1219/dosulepin-deprescribing-information-sheet.pdf> and has been included below.

DLCV: Dosulepin SOP, Version 1, November 2021

Page 2 of 7

The use and application of this SOP does not override the individual responsibility of health care professionals to make decisions appropriate to local need and circumstances of individual patients (in consultation with the patient and/or guardian or carer).

The information regarding how to switch/withdraw Dosulepin is not binding, and each switch should be tailored based on individual patient circumstances and needs.

#### What to switch to

There is no direct antidepressant replacement for Dosulepin. Possible alternatives, include less toxic tricyclic antidepressants (such as [Lofepramine](#) but not *Amitriptyline*), SSRI medications (such as [Sertraline](#)) and SNRI medications (such as [Venlafaxine](#)), or other antidepressants (including [Mirtazapine](#) or [Vortioxetine](#)). The decision of which to use as an alternative should be taken in collaboration with the patient, based on an informed discussion including past treatment history (including tolerability and effect of previous antidepressant medications).

#### How to cross-taper

The Maudsley prescribing guidelines in psychiatry recommend “cautious cross-tapering”. The speed of the

cross-tapering should be judged by monitoring the tolerability of the switch by the individual patient. The following tables are interpretations of the advice given in Maudsley and the BNF.

	Medication	Current dose	Week one	Week two	Week three	Week four
Cautious switch from dosulepin to SERTRALINE	Dosulepin	150mg	75mg	50mg	25mg	Stop
	Sertraline	0mg	0mg	25mg	50mg	50mg

Gradually reduce the dose of dosulepin to 25-50mg/day as per the above withdrawal regimen, and then add in the SSRI. Continue cross tapering and review the sertraline following the switch.

	Medication	Current dose	Week one	Week two	Week three	Week four
Cautious switch from dosulepin to LOFEPRAMINE	Dosulepin	150mg	75mg	50mg	25mg	Stop
	Lofepramine	0mg	35mg	35mg	70mg	70mg

Gradually reduce the dose of dosulepin to 25-50mg/day as per the above withdrawal regimen, and then add in lofepramine cautiously (tablets are scored).

	Medication	Current dose	Week one	Week two	Week three	Week four
Cautious switch from dosulepin to VENLAFAXINE	Dosulepin	150mg	75mg	50mg	25mg	Stop
	Venlafaxine	0mg	0mg	75mg	75mg	75mg

Gradually reduce the dose of dosulepin to 25-50mg/day as per the above withdrawal regimen, then start a low dose of venlafaxine. Following introduction, venlafaxine can be increased if necessary up to 300mg/day (doses over 300mg/day are classified as AMBER 2, and will require specialist initiation).

Please refer to the original Nottingham Dosulepin Deprescribing information sheet [Dosulepin-deprescribing-information-sheet.pdf](#) for additional important information.

#### Further information on the withdrawal of Dosulepin

Some patients may require a slower withdrawal regimen e.g. a reduction by 25mg every week as opposed to reducing by 50mg every week, especially if the patient has been taking Dosulepin for a considerable amount of time. The guidelines say to reduce by **at least 4 weeks** but that has been interpreted as the minimum time in which the medication should be reduced.

A slower withdrawal regimen could be as follows:

Current Dose	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
150mg/day	125mg/day	100mg/day	75mg/day	50mg/day	25mg/day	STOP

**This information is not binding, and the withdrawal regimen should be tailored based on individual patient circumstances and needs.**

The review work will require several face to face or telephone consultations with the patient to assess how they are progressing. It may take a considerable amount of time before a particular case can be closed and then the patient can be followed up as per routine practice procedures. NICE Clinical Knowledge Summaries contains information on how to assess a patient with depression at review <https://cks.nice.org.uk/topics/depression/management/ongoing-management/> which includes the use of a **depression questionnaire** to monitor the patients' progress.

## Audit aims

The aim of the audit is to review all prescribing of Dosulepin, with a view to implementing one of the options detailed in the audit objectives.

## Audit Objectives

100% of Dosulepin prescribing should be reviewed which results in one of the following outcomes, as deemed appropriate for the individual patient:

1. Dosulepin is gradually stopped, as per guidance in PrescQIPP bulletin 126.
2. Dosulepin is switched, via a cautious cross-tapering approach, to an alternative anti-depressant that is appropriate for the individual patient.
3. The patient is referred to a mental health specialist in secondary care for review and support.

## Inclusion Criteria

All patients currently prescribed Dosulepin.

## Exclusion Criteria

No routine exceptions were identified in the NHS England guidance.

## Responsibilities

- All healthcare professionals must ensure they act within their sphere of competence and are up to date with this clinical area before implementation of this SOP.

DLCV: Dosulepin SOP, Version 1, November 2021

Page 4 of 7

The use and application of this SOP does not override the individual responsibility of health care professionals to make decisions appropriate to local need and circumstances of individual patients (in consultation with the patient and/or guardian or carer).

- The GP prescribing lead/designated clinician (DC)\* agrees to the recommendations offered to the practice.
- The practices' PCN/practice Pharmacist will run searches to identify patients and populate the audit sheet.
- The GP/DC is responsible for reviewing patients identified and signing off the changes.
- All parties will ensure that patient confidentiality is respected throughout the process.
- The PCN/practice Pharmacist will ensure that all practice staff are aware of any changes.
- If at any point in the review process a case of prescribing is found that poses a significant safety concern for the patient then that should be brought to the GP's attention as soon as it is practical to do so.

## Process

Prior to commencing this work, ensure you understand local and national policy and guidance regarding the prescribing of Dosulepin, the prescribing of anti-depressant medication and management of depression. Refer to appropriate up to date reference sources (e.g. relevant PrescQIPP bulletins, relevant parts of an up to date BNF and NICE guidance) as necessary.

1. Agree this work with the practices' GP Prescribing Lead or DC and document the following:

Name of PCN/practice Pharmacist who will be working to this SOP	
Job title of PCN/practice Pharmacist who will be working to this SOP	
Name and job title of GP Prescribing Lead/DC	
Signature of GP Prescribing Lead/DC authorising work in accordance with this SOP <b><u>(prior to authorisation, the GP/DC must ensure that this is within the scope of practice of the Pharmacist who will be working to this SOP)</u></b>	
Date of authorisation	
Time frame for completion of work in accordance with this SOP (e.g. within 4 weeks from date of authorisation)	

2. Run a computer search to identify all patients who are currently receiving prescriptions for Dosulepin.
3. Complete audit sheet with the required fields and include information that you feel may be of relevance.
4. Designated Prescribing Lead/DC should review recommendations for suitability on an individual patient basis, referring to the patients' medical records when reviewing audit

results, and authorise appropriate recommendations, including stating how they would like this information communicated with each individual patient by the PCN/practice pharmacist (e.g. GP review/telephone call), including details of follow-up reviews and point of contact for the patient if there are any problems following the medication change process.

5. Changes to be carried out by the designated member of staff acting in accordance with this SOP.
6. Record on patient records, including the name and role of the clinician who has authorised the change, and inform relevant practice staff of any changes made.
7. At all stages ensure appropriate record keeping.
8. Record saving/intervention on MedOptimise under designated practice and QIPP work stream area. **Ensure no patient identifiable information is entered onto MedOptimise.**

## Record keeping for practice staff information

The practice/PCN Pharmacist should agree with the GP Prescribing Lead/DC the method of record keeping for audit results and list of patients who have undergone a medication change so that the practice has a copy of changes made in case of queries. **GP/DC authorisation signatures** must be placed in a designated file held within the practice for future reference.

*\* The term 'Designated Clinician (DC)' refers to a suitably trained GP or non-medical prescriber at the practice who has been assigned, by the GP Prescribing Lead of the practice, to authorise and oversee work at the practice in accordance with this SOP.*

## References

1. NHS England Medicines Value Programme <https://www.england.nhs.uk/medicines-2/value-programme/> <accessed 12.10.2021>
2. NHS ENGLAND (2019). Items which should not routinely be prescribed in primary care: Guidance for CCGs [Online]. Version 2, June 2019. Available at: <https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf>
3. Staffordshire and Stoke on Trent CCGs Prescribing Policy on Drugs of Limited Clinical Value, Version 3, September 2019. Available via: <https://www.northstaffordshirejointformulary.nhs.uk/docs/gcp/Prescribing%20Commissioning%20Policy%20v3.0%20FINAL.pdf?UNLID=5911317402021923125529> <accessed 12.10.2021>
4. Taylor, D. and Barnes, T.R.E., Young, A.H (Eds.) (2018) The Maudsley prescribing guidelines in psychiatry. 13th edn. Chichester: Wiley Blackwell.
5. UKMi October 2019: How do you switch between tricyclic, SSRI and related antidepressants? [https://www.sps.nhs.uk/wp-content/uploads/2019/09/UKMI\\_QA\\_How-do-you-switch-between-MAOI-SSRI-TCA-or-related-ADs\\_update\\_April-2019.pdf](https://www.sps.nhs.uk/wp-content/uploads/2019/09/UKMI_QA_How-do-you-switch-between-MAOI-SSRI-TCA-or-related-ADs_update_April-2019.pdf) <accessed 13.10.2021>
6. Dosulepin Deprescribing Information sheet <https://www.nottinghamshiremedicinesmanagement.nhs.uk/media/1219/dosulepin-deprescribing-information-sheet.pdf> <accessed 12.10.2021>
7. Dosulepin, stopping and switch guidance. NHS East and North Hertfordshire CCG [https://www.enhertscg.nhs.uk/sites/default/files/content\\_files/Prescribing/Local\\_Decisions/Central\\_nervous\\_system/Dosulepin%20E2%80%93stopping%20and%20switching%20guidance.pdf](https://www.enhertscg.nhs.uk/sites/default/files/content_files/Prescribing/Local_Decisions/Central_nervous_system/Dosulepin%20E2%80%93stopping%20and%20switching%20guidance.pdf) <accessed 13.12.2021>
8. NICE do not do recommendation. <https://www.nice.org.uk/donotdo/do-not-switch-to-or-start-dosulepin-because-evidence-supporting-its-tolerability-relative-to-other-antidepressants-is-outweighed-by-the-increased-cardiac-risk-and-toxicity-in-overdose> <accessed 13.10.2021>

9. NICE guidance. Depression in Adults. Recognition and management. 28 October 2009.  
<https://www.nice.org.uk/guidance/CG90> <accessed 13.10.2021>
10. BNF information. Dosulepin Hydrochloride. <https://bnf.nice.org.uk/drug/dosulepin-hydrochloride.html>  
<accessed 13.10.2021>
11. Clinical Knowledge Summaries (CKS) <https://cks.nice.org.uk/topics/depression/management/ongoing-management/> <accessed 13.10.2021>

This document was adapted by Shabana Mahmood and approved by Tunde Kikiowo.

The use of this document is the responsibility of the user, and the CCG will bear no liability for its use.

For any queries, please email [StaffsMedsOptSLA@staffsstokeccgs.nhs.uk](mailto:StaffsMedsOptSLA@staffsstokeccgs.nhs.uk)