

Prescribing of dosulepin is not supported

Thurrock CCG, and Basildon and Brentwood CCG do not support the prescribing of dosulepin due to the significant safety concerns and this position is supported by NHS England.

Dosulepin has been made non-formulary by the Essex Partnership University Trust (EPUT).

Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. NICE CG90: Depression in Adults has a “do not do” recommendation: *“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.”*

In December 2007, the Medicines and Healthcare Regulatory Agency (MHRA) also issued safety advice around prescribing of dosulepin, related to the narrow margin between therapeutic doses and potentially fatal doses.

Recommendations

- Do not initiate dosulepin in any new patients.
- Existing patients should be reviewed to assess their ongoing need and suitability for dosulepin, in view of the associated safety concerns. Patients at risk of suicide should be reviewed as a matter of urgency.
- At this review, consideration should be given to reducing the dose, switching to an alternative or stopping treatment.
- Dosulepin is licensed for the treatment of depressive illness in adults. It should not be prescribed for any unlicensed indication, including anxiety, neuropathic pain or insomnia.
- It is contraindicated in patients who have had a recent myocardial infarction or in patients with heart block of any degree or other cardiac arrhythmias. It is also contra-indicated in mania and in severe liver disease.
- Dosulepin should not be stopped suddenly unless serious side effects have occurred as patients may experience unpleasant discontinuation symptoms. Slowly tapering the dose over three to four weeks can help prevent this.
- Discontinuation symptoms may include anxiety, flu-like symptoms and insomnia. Some people may require a more gradual tapering of the dose if withdrawal symptoms occur. The doses selected and the speed at which they are reduced will need to be individualised for each patient

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. 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:

- 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.

This position is supported by NHS England as part of the items which should not routinely be prescribed in primary care.

Providers commissioned to provide services on behalf of Thurrock CCG and Basildon and Brentwood CCG are reminded that they are required to follow the local joint formulary and prescribing guidance, or relevant Medicines Management agreement.

Position Statement No.	42
Title	Prescribing of dosulepin is not supported
References	<p>1. NICE do not do recommendation October 2009: 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</p> <p>2. Dosulepin: measures to reduce risk of fatal overdose. MHRA Drug Safety Update December 2007: https://webarchive.nationalarchives.gov.uk/http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON084687</p> <p>3. PrescQIPP bulletin 126 Dosulepin (DROP-List): https://www.prescqipp.info/resources/send/313-dosulepin-drop-list/2857-bulletin-126-dosulepin-drop-list</p> <p>4. NHS England guidance on 'Items which should not routinely be prescribed in primary care' (June 2019): https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf</p>
Acknowledgements	Mid Essex CCG Medicines Management Team
Version	1
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