

Policy Statement; prescribing of Dosulepin is not supported.

Mid Essex Clinical Commissioning Group does not support the prescribing of dosulepin due to the evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose.

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

Rationale for reviewing dosulepin prescribing:

- Although dosulepin has been shown to be better tolerated than some alternative antidepressants, this is outweighed by the increased cardiac risk and toxicity in overdose.
- In December 2007, the Medicines and Healthcare Regulatory Agency (MHRA) issued safety advice around prescribing of dosulepin, related to the narrow margin between therapeutic doses and potentially fatal doses.
- NICE has concluded that dosulepin should not be prescribed and issued “do not do” guidance

Recommendations:

- Do not prescribe 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.

Providers commissioned to provide services on behalf of Mid-Essex CCG are reminded that they are required to follow the Mid-Essex CCG formulary and prescribing guidance as detailed in the Medicines Management Service Specification.

See Mid-Essex CCG website – Medicines optimisation page for all prescribing guidance:

<http://midessexccg.nhs.uk/your-health-services/medicines-optimisation>

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| Title | Dosulepin prescribing policy |
| Document reference | DosulepinPOL201708V1.0FINAL |
| Author | Medicines Optimisation Team MECCG |
| Reference: | <p>Dosulepin (DROP-List) PrescQIPP bulletin 126 April 2016 https://www.prescqipp.info/resources/send/313-dosulepin-drop-list/2857-bulletin-126-dosulepin-drop-list</p> <p>Dosulepin: measures to reduce risk of fatal overdose. MHRA Drug Safety Update December 2007 http://webarchive.nationalarchives.gov.uk/http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON084687</p> <p>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> |
| Approved by | Medicines Management Committee |
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| Previous version | Key Changes |
|------------------|-------------|
| N/A | New policy |