

## Position statement on the prescribing of dosulepin

### SW London CCGs\* do not support the prescribing of dosulepin for any indication

Dosulepin should not be prescribed for any indication because evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose. It should not be used as an anxiolytic, for neuropathic pain or for its sedative effects as an aid to sleep.

#### Rationale

- 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.<sup>1</sup>
- NICE Clinical Guideline 90 has concluded that dosulepin should not be prescribed. 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.<sup>2</sup>
- Prescribing of antidepressants should be in line with the relevant NICE guidance. First line antidepressants are generic citalopram and sertraline.
- Dosulepin is contra-indicated 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, in severe liver disease and hypersensitivity to dosulepin or to any of the excipients.<sup>3</sup>

#### References

- 1. <a href="https://www.prescqipp.info/resources/send/313-dosulepin-drop-list/2857-bulletin-126-dosulepin-drop-list/">https://www.prescqipp.info/resources/send/313-dosulepin-drop-list/2857-bulletin-126-dosulepin-drop-list</a>
- 2. National Institute for Health and Care Excellence (NICE). Depression in adults. Clinical Guideline 90. October 2009. Accessed 20/06/15 via https://www.nice.org.uk/guidance/cg90
- 3. Summary of Product Characteristics Dosulepin Hydrocholride 75mg tablets last updated 29/06/2015. <a href="https://www.medicines.org.uk">www.medicines.org.uk</a>. Accessed 09/02/2017
- 4. Taylor D, Paton C, Kapur S. The Maudsley Prescribing Guidelines in Psychiatry. 12th edition. Informa Healthcare, London 2015.
- Medicines and Healthcare products Regulatory Agency (MHRA). Citalopram and escitalopram: QT interval prolongation. Published:12 December 2011
   <a href="http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1439527832975.pdf">http://www.mhra.gov.uk/home/groups/spcpil/documents/spcpil/con1439527832975.pdf</a> . Accessed 15 Feb 2017
- 6. SWLSTG NHS Trust Factsheet 9. Alternatives to prescribing dosulepin for insomnia in Older Adults Guidance for patients <a href="http://www.swlstg-tr.nhs.uk/">http://www.swlstg-tr.nhs.uk/</a>





### **Guidance and recommendation for clinicians**

- Do not start new patients on dosulepin.
- Dosulepin should not be stopped abruptly unless serious side effects have occurred. Slowly tapering the
  dose over at least three to four weeks can help prevent discontinuation symptoms (such as anxiety, flu-like
  symptoms and insomnia).
- People who have been receiving longer term maintenance treatment may need to be tapered for much longer e.g. over six months. The doses selected and the speed at which they are reduced will need to be individualised for each patient.<sup>4</sup>
- Review existing patients to assess their ongoing need and suitability for dosulepin in view of safety concerns. Patients at risk of suicide should be reviewed as a matter of urgency.
- Discuss the choice of a potential alternative antidepressant with the patient and take into account depressive symptoms, relative side effects, physical illness and interactions with any other prescribed medicines.
- Inform the patient of the potential risks of serious cardiac side-effects with dosulepin, even at therapeutic doses, associated symptoms and what to do if they experience any of them.
- Alternative non-antidepressant options may be suitable for patients taking dosulepin for other indications e.g. sleep hygiene advice if used for insomnia (see below).

## Changing dosulepin to a selective serotonin reuptake inhibitor (SSRI)<sup>1</sup>

- As with all changes, these should be tailored to the individual patient. For advice, contact Medicines
  Information at Springfield University Hospital on 020 3513 6829 or, for Croydon Clinicians, South London
  and Maudsley NHS Foundation Trust on 0203 2282317.
- Gradually reduce the dose of dosulepin to 25mg/day as per the suggested withdrawal regimen below. Once the dose of dosulepin is 25mg/day, introduce the SSRI at the usual starting dose (note elderly patients should be started at half the usual adult starting dose). Then slowly withdraw the remaining dosulepin over at least 5 to 7 days. For patients who have been taking dosulepin long-term, the withdrawal regimen may need to be slower and with smaller decreases in dose. This is a clinical decision to be made on an individual patient basis.
- If changing to citalopram, the maximum dose for adults is now 40mg daily (20mg daily for over 65s) in view of the European-wide review into the risks of QT interval prolongation.<sup>5</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

# Guidance for patients currently taking dosulepin, carers and guardians<sup>6</sup>

- Dosulepin is an antidepressant, which can be used for anxiety, depression or insomnia. On stopping, 'discontinuation' symptoms can occur. Symptoms are usually mild and may be lessened by slowly lowering the dose in small steps; they are excessive saliva production, runny nose, diarrhoea or abdominal cramps. Doses used for insomnia are usually low and may be less likely to cause 'discontinuation' symptoms.
- Dosulepin is an old medicine that is unsafe when taken in large doses. Accidentally taking too much has led to deaths across the country. National regulatory bodies now suggest that all dosulepin prescriptions should be reviewed over concerns of the likelihood of harm to patients.
- If being used as an antidepressant your doctor will discuss with you a slow reduction of the dose, taking between 1 and 6 months.
- If being used to help sleep: Sleep hygiene aims to make you more aware of the different factors that may affect sleep. Your GP may advise you to:
  - Establish fixed times for going to bed and waking up.
  - Maintain a comfortable sleeping environment (not too hot, cold, noisy or bright).
  - Avoid napping during the day, caffeine, nicotine and alcohol within six hours of going to bed.
  - Avoid exercise within four hours of bedtime (exercise earlier in the day is beneficial).
  - Avoid eating a heavy meal late at night and watching or checking the clock throughout the night.
  - Keep a sleep diary to monitor the progress of treatment, noting duration of sleep, diet and exercise.

Further information on good sleep hygiene and non-pharmacological techniques may be found at http://www.nhs.uk/Livewell/insomnia/Pages/bedtimeritual.aspx